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Report No. 25



AD-A216 692

# CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT

30 September 1989

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DEPARTMENT OF CLINICAL INVESTIGATION

Fitzsimons Army Medical Center  
Aurora, Colorado 80045-5001

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| REPORT DOCUMENTATION PAGE   |                       | READ INSTRUCTIONS<br>BEFORE COMPLETING FORM                    |
|---|-----------------------|--|
| 1. REPORT NUMBER<br>25  | 2. GOVT ACCESSION NO. | 3. RECIPIENT'S CATALOG NUMBER                                  |
| 4. TITLE (and Subtitle)<br>Annual Research Progress Report (U)  |                       | 5. TYPE OF REPORT & PERIOD COVERED<br>ANNUAL FY 89             |
|   |                       | 6. PERFORMING ORG. REPORT NUMBER                               |
| 7. AUTHOR(s)<br>SHANNON M. HARRISON, LTC, MC  |                       | 8. CONTRACT OR GRANT NUMBER(s)                                 |
| 9. PERFORMING ORGANIZATION NAME AND ADDRESS<br>Department of Clinical Investigation<br>Fitzsimons Army Medical Center<br>Aurora, Colorado 80045-5001  |                       | 10. PROGRAM ELEMENT, PROJECT, TASK<br>AREA & WORK UNIT NUMBERS |
| 11. CONTROLLING OFFICE NAME AND ADDRESS<br>Office of Deputy Commander (HSHG-ZB)   |                       | 12. REPORT DATE<br>30 September 1989                           |
|   |                       | 13. NUMBER OF PAGES<br>380 pages +                             |
| 14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)<br>U.S. Army Health Services Command<br>ATTN: HSHN-I<br>Fort Sam Houston, Texas 78234-6060  |                       | 15. SECURITY CLASS. (of this report)<br>Unclassified           |
|   |                       | 15a. DECLASSIFICATION/DOWNGRADING<br>SCHEDULE                  |
| 16. DISTRIBUTION STATEMENT (of this Report)<br>Approved for public release, distribution unlimited  |                       |  |
| 17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)<br>N/A   |                       |  |
| 18. SUPPLEMENTARY NOTES<br><br>The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.   |                       |  |
| 19. KEY WORDS (Continue on reverse side if necessary and identify by block number)<br><i>Clinical Medicine</i><br>Unit summary; research protocols (objective, technical approach, progress); publications; presentations. (S) <i>W</i>   |                       |  |
| 20. ABSTRACT (Continue on reverse side if necessary and identify by block number)<br>Subject report identifies these individuals who are conducting investigative protocols at Fitzsimons Army Medical Center. An abstract of each protocol giving abbreviated technical approach, objectives, and progress is presented.<br><i>Keywords:</i> |                       |  |

REPORTS CONTROL SYMBOL MED-300

ANNUAL PROGRESS REPORT

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DEPARTMENT OF CLINICAL INVESTIGATION  
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AURORA, COLORADO 80045-5001

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## FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1989 along with other known presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 40-23, as amended, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations. In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is grateful to the Center's Commander, BG Thomas E. Bowen and all of the professional and administrative staff for departments and directorates who have furthered the mission of Clinical Investigation Department at Fitzsimons through their cooperation and extra effort as reflected in this report. I should like to particularly recognize the outstanding work and dedication and wholehearted corroboration of all of the Services' within Clinical Investigation Department, the Deputy Chief, LTC Leo A. Andron, the Research Protocol Specialist, Ms. Marcia Bilak, and Ms. Chris Montoya, Secretary, without whose assistance and support beyond the call of duty this year's progress and its report would not have been possible.

*Shannon M. Harrison LTC MC*

SHANNON M. HARRISON  
LTC, MC  
Chief, Department of  
Clinical Investigation

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## UNIT SUMMARY

Clinical Investigation efforts by FAMC personnel in FY 89 culminated in the publication of 198 articles and 135 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1989, there were 265 research protocols on the DCI register. Of these, 217 projects were ongoing, 34 projects completed, 14 projects terminated, and for this FY there were 66 new registrations.

### Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e., active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medicine. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

### Technical Approach:

This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18,

Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Manpower: current authorized strength is outlined.

| Description       | Grade | MOS   | Br  | Auth | Req | Act | Name                  | Rank |
|-------------------|-------|-------|-----|------|-----|-----|-----------------------|------|
| C, Dept Clin Inv  | 05    | 60P9B | MC  | 1    | 1   | 1   | HARRISON              | LTC  |
| C, Micro Svc      | 05    | 68A00 | MSC | 1    | 1   | 1   | Andron                | LTC  |
| C, Biomet & Resh  | 04    | 68T00 | MSC | 0    | 1   | 1   | Sherman               | MAJ  |
| C, Biochem Svc    | 04    | 68C9C | MSC | 1    | 1   | 1   | White                 | MAJ  |
| C, Immunol Svc    | 04    | 68E00 | MSC | 1    | 1   | 1   | Stewart               | MAJ  |
| C, Cell Phys Svc  | 03    | 68J00 | MSC | 1    | 1   | 1   | Ferris                | CPT  |
| C, Animal Res Svc | 04    | 64C9B | VC  | 1    | 1   | 1   | Trahan                | MAJ  |
| NCOIC-Med Lab     | E7    | 92B4R |     | 1    | 1   | 0   |                       | SFC  |
| Operating Rm Sp   | E5    | 91D2R |     | 1    | 1   | 1   | Haynes                | SGT  |
| Bio Sci Asst      | E6    | 01H3R |     | 1    | 1   | 0   |                       | SSG  |
| Bio Sci Asst      | E6    | 92B3R |     | 1    | 1   | 01  |                       | SSG  |
| Bio Sci Asst      | E5    | 01H3R |     | 1    | 1   | 1   | Sanders               | SGT  |
| Vet Sp            | E6    | 91T3R |     | 1    | 2   | 1   | Barrett               | SSG  |
| Vet Sp            | E5    | 91T2R |     | 1    | 1   | 1   | Lamb                  | SGT  |
| Bio Sci Asst      | E4    | 01H1R |     | 1    | 1   | 1   | Cruz-Saez             | SP4  |
| Bio Sci Asst      | E4    | 01H1R |     | 1    | 1   | 1   | Williams              | SP4  |
| Bio Sci Asst      | E4    | 01H1R |     | 1    | 1   | 1   | Mendez                | SP4  |
| Bio Sci Asst      | E4    | 01H1R |     | 1    | 1   | 1   | Galvin                | SP4  |
|                   | E4    | 01H1R |     | 1    | 1   | 0   |                       |      |
| Supv Res Chem     | 13    | 1320  | GS  | 1    | 1   | 0   |                       |      |
| Microbiologist    | 11    | 0403  | GS  | 3    | 3   | 3   | Lima<br>Paine<br>Hoyt |      |

| Description                   | Grade | MOS  | Br | Auth | Req | Act | Name   | Rank |
|-------------------------------|-------|------|----|------|-----|-----|--|------|
| Microbiologist                | 09    | 0403 | GS | 3    | 6   | 3   | Morse<br>Tessier<br>Muehlbauer   |      |
| Med Technologist              | 11    | 0644 | GS | 0    | 1   | 1   | Rush   |      |
| Med Technologist              | 09    | 0644 | GS | 0    | 6   | 5   | Ramirez (Term)<br>Chadwick (Term)<br>Pinney (Term)<br>Sachanandani (Term)<br>Gulati (Term) |      |
| Med Technician                | 07    | 0645 | GS | 1    | 1   | 1   | Nelson   |      |
| *Research Chem                | 11    | 1320 | GS | *4   | *3  | *3  | Noble<br>Williams<br>Stewart   |      |
| Bio Lab Tech<br>(Animal)      | 09    | 0404 | GS | 1    | 1   | 1   | Mercill  |      |
| Animal Caretaker<br>(Foreman) | 04    | 5048 | WS | 1    | 1   | 1   | Jones  |      |
| Research Prot Sp              | 09    | 0301 | GS | 1    | 1   | 1   | Bilak  |      |
| Animal Caretaker              | 05    | 5408 | WG | 1    | 3   | 2   | Chase<br>Hitchcock   |      |
| Secretary                     | 06    | 0318 | GS | 1    | 1   | 1   | Montoya  |      |

\* - The four GS11 chemist requirements are as follows:

One authorization changed to a GS644 Medical Technologist (open)  
Two authorizations filled with GS11 Chemists  
One overhire on board GS11 Chemist (required but not authorized)

#### Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

|     |                    | FY 87      | FY 88      |
|-----|--------------------|------------|------------|
| OMA | Civilian Personnel | 653,076.36 | 668,953.   |
|     | Contracts          | 39,964.93  | 41,514.    |
|     | Supplies           | 297,881.20 | 218,000.   |
|     | Ceep Equipment     | 17,215.14  | 28,599.    |
|     | Travel             | 9,076.18   | 6,552.     |
| OPA | MEDCASE            | 241,152.77 | 282,809.40 |

### FY 89 Budget Summary

|                     |       |                   |          |
|---------------------|-------|-------------------|----------|
| Mission TDY         | 2772. | Mission Contracts | 18,800.  |
| Short Course TDY    | 2397. | Supplies          | 200,000. |
| Civilian Tng Tvl    | 862.  | Equipment CEEP    | 4,350.   |
| Civ. Consultant Tvl | 728.  |                   |          |

(does not include personnel)

|                    |          |                     |
|--------------------|----------|---------------------|
| MEDCASE HSC funded | 395,668. | electron microscope |
|                    | 183,454. | other               |

### GRANTS

#### USAMRDC

Prospective Double Blind Study of Zidovudine (AZT) in Early Stage HIV Infection. \$115,000

A Double Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Gram-Negative Sepsis/Gram Negative Septic Shock. \$30,000

Prevention of Nosocomial Pneumonias and Stress Gastroduodenal Ulcers in Ventilated Patients. \$88,620

#### Veterans Administration (VA)

|                                  |          |
|----------------------------------|----------|
| VA Funds (Sherman)               | \$81,000 |
| Colorado State Health Department | \$5,000  |

### Personnel

|             | Authorized | Required | Assigned |
|-------------|------------|----------|----------|
| Officers    | 6          | 7        | 7        |
| Enlisted    | 12         | 12       | 9        |
| Civilian    | 15         | 34       | 24       |
| VA Civilian | 2          | 2        | 2        |

|                          |              |
|--------------------------|--------------|
| Military Personnel FY 89 | \$1,260,000. |
| Civilian Personnel FY 89 | \$2,006,859. |

Publications FY89 \$6,759

#### Animal Resources Service - FY 89

A new steam sterilizer and a new ethylene oxide sterilizer were installed in support of surgical services. Additional direct support included a new surgical table, a new anesthesia machine (3-gas; with NIPB, CO<sub>2</sub>, and SAO<sub>2</sub> monitors), and upgrading of the electrical supply system in both surgical suites. A used "Life Pac 6" defibrillator/ECT monitor was acquired thru the Property Disposal Office at FAMC.

A series of training files was acquired to support the educational and training of new animal-use investigators. A services contract was established with a local veterinary laboratory to provide for research animal diagnostic clinical pathology.

Eight members of the Laboratory Animal Care and Use Committee and the DCCs, FAMC, attended a 3-day workshop on the "Public Health Service Policy on the Humane Care and Use of Laboratory Animals and Contemporary Issues Confronting Human Research Institutional Review boards". MAJ Trahan and Mr. Jones attended the National AALAS meeting, held in Detroit, MI, during October, 1988. MAJ Trahan completed requirements for licensure by the Colorado State Board of Veterinary Medicine, and for accreditation, state of Colorado, by the United State Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services.

#### Biochemistry Service - FY 89

1989 continues the upgrade and improvement of the Biochemistry Service. We are making the final push to complete our reorganization. The construction highlight of the year is the renovation of about 400 square feet of lab space on a self help project. One of our senior chemists is the project leader. He tore out the existing wall, installed new cabinets and painted the room. Electrical and plumbing improvements completed the project. The new lab area houses an amino acid analyzer.

We support many interesting projects. The Perkin-Elmer 5100-PC Atomic Absorption Spectrophotometer provides results for a blood lead protocol. We are working on cadmium, arsenic, and aluminum assays. Our gamma counter counts our <sup>125</sup>I assays for glucagon, and B2-microglobulin. We support a passive smoking protocol, HIV research, and enzyme kinetics protocols with our new Beckman BIOMEK 1000 Automated ELISA work station. Our HPLC lab produces three dimensional chromatograms with the addition of the Waters 990+ photo diode array detector. It allows us to gather large amounts of information in a short amount of time. The 990+ supports an allergy protocol where we are purifying proteins from extracts of plants that people may be allergic to.

Our collaboration with outside academic, State and Federal agencies continues. We have developed an amino acid specialty lab in collaboration with the University of Colorado Health Sciences Center. Our Atomic Absorption lab can analyze selected heavy

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Our collaboration with outside academic, State and Federal agencies continues. We have developed an amino acid specialty lab in collaboration with the University of Colorado Health Sciences Center. Our Atomic Absorption lab can analyze selected heavy

metals in biological fluids. We work with the Colorado Department of Health assessing blood lead levels. We started a collaborative endocrine project with Denver University. Our scientists also travel to other local federal laboratories to lend their technical expertise, especially in the field of Gas Chromatography.

#### Cell Physiology Service - FY 89

Increased research opportunity was seized from disaster after a sprinkler main pipe broke and flooded the electron microscope facility. The service was able to replace and upgrade the destroyed equipment with a new Scanning Transmission Electron Microscope which also has x-ray analysis capabilities. This is the most sophisticated electron microscope in medical/biological research in use in the Denver Metro area. When completely on line, it will permit inhouse and major collaborative ultrastructural research efforts.

Of continuing importance is the successful use of nude mice from the CPS colony as the support system for a human skin model. This model which is applicable for many human skin research projects is currently being used to investigate the biology of cutaneous lupus. The study is being carried out in collaboration with the CPS; the Dermatology Service FAMC; and the Dermatology Department, University of Colorado Health Sciences Center.

CPS also supported cell biology aspects of research being conducted in growth hormone treatment, erythroid burst forming growth, hypoxia of newborn intestine, keratinocyte growth and hair growth. These studies used the service's tissue culture, histochemistry, and light microscope facilities. Importantly, the technicians of the service used their talents to help the investigators surmount technical problems unique to each of these studies.

#### Clinical Biometrics and Research Design Service - FY 89

The Psychophysiology and Biostatistics Service has been renamed the Clinical Biometrics and Research Design Service to more closely reflect its actual functions within DCI. The service's missions are to (1) provide professional support to all MEDCEN staff and students in design and analysis of clinical and basic science studies, (2) provide technical support for data management, data entry, and data reduction when the requesting department's resources are insufficient, (3) coordinate the core research curriculum training program required for all Army MEDCENS by HSC, (4) encourage and aid in providing opportunities for research related efforts of staff and students and, (5) provide a modern Psychophysiology/Pain Evaluation Laboratory for clinical and research evaluations as well as psychophysiological treatments. During the service's second year of operation, contract services were arranged to support a part time, masters level statistical assistant and a temporary GS7 data manager position was approved. All first and third year orthopedic residents participated in one or two month research rotations during which they were relieved of

all regular clinical duties. Seminars on research design and statistical analysis were presented to three services outside of Orthopedics and Clinical Investigation. Numerous investigators have been helped to design and analyze studies. Research has demonstrate (1) relationships between muscle tension patterns recorded continuously in the normal environment and onset of tension headaches and (2) relationships between thermographic and surface electromyographic patterns to results of standard evaluations of low back pain subjects.

#### Immunology Service - FY 89

The Immunology Service continues to maintain its reputation as one of the premier military flow cytometry centers. Analysis of cell surface antigens of both normal and leukemic cells, DNA content of leukemic and solid tumors, and neutrophil activation studies still constitute a majority of our workload. The Service has again been tasked with hosting the 3rd Annual Tri-Service Flow Cytometer Quality Assurance Workshop to be conducted the last week of November. The HIV Natural History protocol will continue to follow HIV positive individuals within the Fitzsimons health care region even though the codes have been broken for the AZT protocol and the study will soon terminate. The Van Wildebrand's protocol with the Departments of Pathology and Medicine has been stagnant for about six months and will probably terminate due to lack of clinical samples. The allergy therapy protocol continues to progress with increasing interest in antigen-specific lymphocyte sub-population assays as they become more reliable. The Service has also developed a new non-scintillation analytical method for the quantitation of DNA incorporated tritiated thymidine for the analysis of lymphocyte activation and transformation. This new method greatly increases reliability and accuracy while decreasing both labor costs and radioactive wastes when compared to standard techniques.

The Service has also procured and has placed in operation an advanced statistical and graphics handling system which produces professional grade graphics for both publications and presentations. Preliminary work is beginning to test the feasibility for adapting rate nephelometric technologies for HIV antigen and antibody analysis. Additionally, plans are being formulated which will allow the Service to expand into the area of protein synthesis and sequencing in support of Rheumatology and Allergy/Immunology initiatives for the study of relatedness of bacterial and HLA antigens as they influence autoimmune diseases.

#### Microbiology Service - FY 89

An in-house ELISA test for over 30 antigens of *M. avium* serovars was successfully applied to sera from over 200 HIV seropositive patients. The results showed over 40% of these patients have antibodies to one or more serovars. The results are being incorporated into a manuscript for publication. The mycobacteriology section maintains its excellent record on CAP



proficiency survey and the lab has been CAP accredited for three more years.

The AZT (Zidovudine) treatment study was stopped as originally designed after 218 patients were enrolled and several other much larger studies sponsored by the NIH clearly showed benefit from early treatment. Patients on the placebo arm of this study were converted to drug and data from the study is being analyzed for validation for the laboratory observed changes in P-24 antigen, B-2-microglobulin, culture results, and helper-suppressor and killer cells. While the clinical endpoints of this study would not reach numerical significance, the value of the laboratory data and improved treatment of patients is unquestionable. The low near term toxicity of drug at 800mg/day in early HIV infection was an additional finding of value. These results are being incorporated into publishable manuscripts.

## HUGH MAHON LECTURESHIP AWARD COMPETITION - 1989

This student research award was established in 1950 and honors the late Colonel Hugh W. Mahon, MC, USA, Retired, who was Chief, Department of Pathology, Fitzsimons Army Medical Center, for 12 years. The lectureship consists of the presentation of papers judged best from among those submitted by officers in training status at FAMC.

This year the Hugh Mahon Lectureship Award Competition was expanded so submissions could compete in categories of retrospective or prospective clinical studies, basic laboratory investigations, and literature reviews/case reports. This year's 41 submissions was not only the largest number ever but also contained a more diverse and sophisticated sample of our students' work than seen in previous years.

Judging was done by the members of the FAMC clinical teaching staff and a panel of distinguished university and community professors. Manuscripts were scored on originality and medical significance, experimental design, presentation and interpretation of data, and literary quality.

A Grand Prize Winner was chosen from among the five finalists in all three categories based on the presentation and question-and-answer period during the Hugh Mahon Lectureship Conference. The finalists received Army Achievement Medals, and the Grand Prize Winner was awarded the Army Commendation Award. The finalists for 1989 are as follows:

### Laboratory Investigation

Grand Prize and 1st place

Anthony R. Henry, LTC, MC, Allergy-Immunology

An In-Vitro Animal Model for Beta-Blocker Induced Bronchoconstriction.

2nd place Anthony Colpini, MAJ, MC, Orthopedic Surgery

Biomechanical and Histologic Analysis of Achilles Tendon Healing After Open and Percutaneous Repair in a Rabbit Model.

### Clinical Study

1st Place William Caras, MAJ, MC, Pulmonary Disease

Ventilatory Effects of Transtracheal Oxygen Therapy.

2nd Place Grant C. Olson, CPT, MC, Allergy-Immunology

Food Induced Migraine Headache: Search for Immunologic Mechanisms.

### Literature Review/Case Report

R. Todd Hockenbury, CPT, MC, Orthopedic Surgery

Predictors of Nonprogression in Small Idiopathic Scoliotic Curves.

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(C) = Protocol Related

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#### Orthopedic Service

Andrews JR, Grood ES, McKenzie P, Gillogly SD: PCL Anatomy and Isometry. Presented: The Knee - Current Concepts, American Academy of Orthopaedic Surgeons, Hilton Head, SC, April 1989.

Andrews JR, McKenzie P, Gillogly SD: Arthroscopic ACL Reconstruction. Presented: The Knee - Current Concepts, American Academy of Orthopaedic Surgeons, Hilton Head, SC, April 1989. (C)

Colpini AW, Stahl E: Arthroscopic Anterior Cruciate Ligament Reconstruction. Presented: Annual Meeting Western Orthopaedic Association, Honolulu, HI, October 1988; Annual Meeting Society of Military Orthopaedic Surgeons, Williamsburg, VA, December 1988. (C)

Corpe RS: Complications in Total Knee Arthroplasty. Presented: Anderson Orthopaedic Research Institute, Washington, DC, 1988.

Corpe RS: Preoperative Planning in Total Knee Arthroplasty. Presented: Anderson Orthopaedic Research Institute, Washington, DC, 1988.

Corpe RS: Unicompartamental Knee Replacement. Presented: Anderson Orthopaedic Research Institute, Washington, DC, 1988.

Gillogly SD, Callaghan JJ, McMahon K, Berry BH: Hip Lesions Mimicking Osteoarthritis. Presented and exhibited: Annual Meeting American Academy of Orthopaedic Surgeons, February 1989.

Hahn DB: Back Deformities. Presented: 15th Annual Primary Care Orthopaedics, Aspen, CO, August 1989.

Hahn DB: Group Screening for Sports Participation. Presented: 15th Annual Primary Care Orthopaedics, Aspen, CO, August 1989.

Hahn DB: Pediatric Back Pain. Presented: 15th Annual Primary Care Orthopaedics, Aspen, CO, August 1989.

Hockenbury RT, Johns JC: A Biomechanical Comparison of Open Repair Versus Percutaneous Repair of Achilles Tendon Ruptures. Presented: Annual Meeting Western Orthopaedic Association, Honolulu, HI, October 1988; annual Meeting American Association of Orthopaedic Surgeons Subspecialty Foot and Ankle Society, Las Vegas, Nevada, February 1989. (C)

Hrutzkay JM, Eilert RE: Operative Lengthening of the Lower Extremity and Associated Psychological Aspects. Presented: Mid Central States Orthopaedic Society Annual Meeting, Lake of the Ozarks, MO, June 1989.

Johns JC: Fracture of the Distal Forearm and Wrist. Presented: 15th Annual Primary Care Orthopaedics, Aspen, CO, August 1989.

Johns JC: Fractures and Dislocations of the Hand. Presented: 15th Annual Primary Care Orthopaedics, Aspen, CO, August 1989.

Johns JC: Soft Tissue Injuries/Infections of the Hand. Presented: 15th Annual Primary Care Orthopaedics, Aspen, CO, August 1989.

Johns JC: Trauma to the Adult Hand. Presented: 15th Annual Primary Care Orthopaedics, Aspen, CO, August 1989.

#### Otolaryngology Service - Speech Language Rehabilitation Section

Hasbrouck JM: Behavioral Therapy Programming for Stuttering: Adults and Children. Presented: Colorado Speech-Language-Hearing Foundation Sponsored Seminars, Denver, CO, October 1988.

Hasbrouck JM: Auditory Perceptual Problems in Nonorganic Hearing Disorder. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Denver, CO, April 1989.

Hasbrouck JM: A Visit to Reality: Current Behavioral Approaches to Stuttering Therapy. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Denver, CO, April 1989.

Lowry MF: Laryngectomy Visitor Training Needs. Presented: American Cancer Society, Colorado Chapter, Sterling, CO, March 1989.

Lowry MF: Sertoma/CSHA Affiliation. Presented: Sertoma Mid-Winter Conference, Denver, CO, March 1989.

Lowry MF: Communication for Laryngectomees. Presented: William Beaumont Army Medical Center Laryngectomy/Dysphagia Workshop, El Paso, TX, May 1989.

Lowry MF: Establishing a Laryngectomy Club. Presented: American Cancer Society, Colorado Chapter, Grand Junction, CO, May 1989.

Snelling TM: Multidisciplinary Needs of Otitis Media Children. Presented: Convention on Pediatric Controversies, Denver, CO, February 1989.

Snelling TM, Down MP, Klein JO, Bluestone CD, Friel-Patti S, Gabbard S: Community Management of Children with Recurrent Otitis Media. Presented: American Speech-Language-Hearing Association Annual Convention, Boston, MA, October 1988.

Snelling TM, Ferrer-Vincent ST, Scharfenaker SK: A Multidisciplinary Otitis Media Clinic for Children. Presented: American Speech-Language-Hearing Association Annual Convention, Boston, MA, October 1988.

Snelling TM: Current Issues and Methods in the Use of Supportive Personnel. Presented: American Speech-Language-Hearing Association Annual Convention, Boston, MA, October 1988.

Snelling TM, McMahan DA: The Missing Step in Language Stimulation. Presented: Colorado Speech-Language-Hearing Association Annual Convention, Denver, CO, April 1989.

#### Otolaryngology Head and Neck Surgery Service

Carnel SB, Lepore ML: Subset Immune Deficiency Disorder Manifesting as Chronic Otitis Media. Presented: Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, September 1989.

Eusterman VD, Lepore ML: Physiologic Mandibular Translation for Optimum Surgical Access to the Carotid Sheath. Presented: Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, September 1989.

Eusterman VD, Barrs DM, Casey KF, Henderson RH: Malignant Glomus Tumor of the Temporal Bone. Presented: Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, September 1989.

Eusterman VD, Barrs DM, Casey KF, Heffner DK: A Low Grade Aggressive Papillary Adenocarcinoma of Probable Endolymphatic Sac Origin. A Newly Recognized Entity. Presented: Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, September 1989.

Lepore ML, Goldstein JL: Rehabilitative Aspects of the Hearing Impaired Geriatric Patient. Presented: Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, September 1989.

Sargent DW, Lepore ML, Lanier DM, Yakes WF: Sequential Preoperative Embolization of Vascular Head and Neck Tumor. Presented: Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, September 1989.

Woods TR, Lepore ML: Retropharyngeal Abscess Versus Retropharyngeal Cellulitis - Controversy Resolved with Computed Tomography. Presented: Annual Meeting of the American Academy of Otolaryngology-Head and Neck Surgery, New Orleans, LA, September 1989.

Yoshida GY, Hamaker RA: Primary Voice Restoration at Laryngectomy. Presented: Middle Section Triological Society Meeting, Indianapolis, IN, January 1989.

Yoshida GY, Hamaker RA: Modifications of the Cornal Forehead Lift: Presented: Midwestern Meeting American Academy of Facial Plastic and Reconstructive Surgery, Indianapolis, IN, December 1988.

#### Ophthalmology Service

Colon LE, Enzenauer RJ: Corneal Thinning as Sole Manifestation of Active Undifferentiated Connective Tissue Disease. Presented: Southern Medical Society Meeting, November 1988.

Colon LE: an Outbreak of Epidemic Kerato Conjunctivitis Due to Adenovirus Type-8 in a Military Hospital. Presented: Southern Medical Association Meeting to be held November 1989. (C)

Cornell FM: Lens and Iris Injuries. Presented: 7th Annual Current Concepts in Ocular Trauma, Letterman Army Institute of Research, Anterior Segment Symposium, San Francisco, CA, 1989.

Cornell FM: Extracapsular Cataract Technique; Capsulotomy; Phakoemulsification Anterior Virectomy. Presented: Uniformed Services University of Health Sciences, Tri Service Resident Cataract Surgery Course, Bethesda, MD, 1989.

Enzenauer RW, Mauldin WM: Boxing Related Ocular Injuries in the US Army 1980-1985. Presented: 82nd Annual Scientific Assembly of the Southern Medical Association Section on Ophthalmology, New Orleans, LA, September 1988. (C)

Enzenauer RW, Montrey JS, Enzenauer RJ, Mauldin WM: Boxing Injuries in the US Army 1980-1985. Presented: William Beaumont Trauma Symposium, El Paso, TX, November 1988. (C)

George RK: The Management of Basic Ocular Injuries. Presented: United States Army Health Clinic, Birdlach, West Germany, February 1989.

Pernelli DR: Use of GORE-TEX<sup>®</sup> in Repair of Lid Defects in Rabbits. Presented: Colorado Ophthalmological Society, University of Colorado Health Sciences Center, Denver, CO, 1989. (C)

Stock JG: Retinal Findings of Systemic Light Chain Deposition Disease. Presented: Colorado Ophthalmologic Society, May 1989.

Walton WT: Abortive Cryptophthalmos: A Case Report. Presented: Colorado Ophthalmologic Society, May 1989.

#### DEPARTMENT OF CLINICAL INVESTIGATION

Arena J, Sherman R, Bruno G: Professionals' and Low Back Pain Patients' Expectations of Differences in Response Patterns on the MMPI as a Function of Presence or Absence of Chronic Pain. Presented: 20th Annual Meeting of the Association for Applied Psychophysiology, San Diego, CA, March 1989. (C)

Arena J, Sherman R, Bruno G: Electromyographic Recordings of Low Back Pain Subjects in Different Positions During Low and High Pain Levels. Presented: 20th Annual Meeting of the Association for Applied Psychophysiology, San Diego, CA, March 1989. (C)

Arena J, Sherman R, Bruno G: The Relationship Between Humidity Level, Temperature, and Phantom Limb Pain: Preliminary Analysis. Presented: 20th Annual Meeting of the Association for Applied Psychophysiology, San Diego, CA, March 1989. (C)

Sherman R, Sherman C: Relationships Between Continuous Environmental Recordings of Posterior Trunk Muscle Tension and Patterns of Low Back Pain and Tension Headaches. Presented: 20th Annual Meeting of the Association for Applied Psychophysiology, San Diego, CA, March 1989. (C)

Sherman R, Sherman C, Grana A: Occurrence of Acute Muscle Contractions in the Residual Limbs of Amputees Preceding Acute Episodes of Phantom Limb Pain. Presented: 20th Annual Meeting of the Association for Applied Psychophysiology, San Diego, CA, March 1989. (C)

Sherman R, Arena JG, Bruno GM, Smith JD: Precursor Relationships Between Stress, Physical Activity, Meteorological Factors, and Phantom Limb Pain: Results of Six Months of Pain Logs. Presented: Joint Meeting of the Canadian and American Pain Societies, Toronto, Canada, November 1988. (C)

Sherman R, Arena JG, Searle J, Sherman CJ: Relationships Between Low Back Pain, Stress, and Continuous Recordings of Paraspinal Surface EMG and Movement in Patients' Normal Environments. Presented: Joint Meeting of the Canadian and American Pain Societies, Toronto, Canada, November 1988. (C)

#### DEPARTMENT OF PEDIATRICS

Carter BS, DiGiacomo JE, Balderston SM, Wiggins JW, Merenstein GB: Disproportionate Septal Hypertrophy in Erythroblastosis Fetalis. Presented: 14th Annual Conference on Neonatal/Perinatal Medicine. American Academy of Pediatrics District VIII Section on Perinatal Pediatrics, Anchorage, AK, May 1989.

Carter BS, Moores R, Meschia G, Battaglia FC: Lactate Utilization in the Mid-Gestation Fetal Lamb. Presented: Conference on Military Perinatal Research at Aspen (COMPRA) Aspen, CO, July 1989.

Carter BS, Anderson BA, Frank CG, Pierce JR: Military Neonatologists and Bioethical Decision Making. Presented: Conference on Military Perinatal Research at Aspen (COMPRA) Aspen, CO, July 1989.

Frank CG: National Faculty/Course Instructor American Academy of Pediatrics/American Heart Association Instructors Course in Neonatal Resuscitation, Denver, CO, April 1989.

Graham LM, Vasil ML, Voekel NK, Stenmark KR: Chronic Pseudomonas Pneumonia Results in Reduced Pulmonary Vasoreactivity and Elevated Pulmonary Artery Pressure. Presented: American Thoracic Society, Cincinnati, OH, May 1989. (C)

Graham LM, Vasil ML, Voekel NF, Stenmark KR: Pulmonary Vascular Effects of Chronic Pseudomonas Pneumonia. Presented: Uniformed Services Section, American Academy of Pediatrics, Honolulu, Hawaii, March 1989. (Finalist Ogden Bruton Award) (C)

Graham LM, Vasil ML, Voekel NF, Stenmark KR: Pulmonary Vascular Effects of Chronic Pseudomonas Pneumonia-Potential Pathophysiologic Mechanisms. Presented: 4th Annual North American Cystic Fibrosis Conference, Tarpon Springs, Florida, October 1989. (C)

Kinsella JP: Cardiac Output and Organ Blood Flow in the Premature with Hyaline Membrane Disease. Presented: Conference on Military Perinatal Research at Aspen (COMPRA) Aspen, CO, July 1989.

Kinsella JP: Cardiopulmonary Effects of High Frequency Ventilation in the Premature with HMD. Presented: Conference on Military Perinatal Research at Aspen (COMPRA) Aspen, CO, July 1989.

Mosijczuk AD: Pre-Radiation Chemotherapy in Advanced Medulloblastoma: Preliminary Report of POG 8695. Presented: Poster presentation, International Symposium of Pediatric Neuro-Oncology, Seattle, WA, June 1989. (C)

#### DEPARTMENT OF PATHOLOGY AND ALS

Reddy VVB: Value of Altered Bone Marrow Topography in Diagnosis of Myelodysplastic Syndromes. Presented: US and Canadian Academy of Pathology Annual Meeting, San Francisco, CA, March 1989.

Reddy VVB, Ownby JL: Improved Detection of Low Density Antigens in Tissues by Modified Modulation Contrast Microscopy. Presented: US and Canadian Academy of Pathology Annual Meeting, San Francisco, CA, March 1989.

#### DEPARTMENT OF NURSING

Frelin AJ: Patient Classification, The Workload Management System for Nursing, A Management Perspective. Presented: AMEDD Chief Wardmaster's Conference, Denver, CO, June 1989.

Frelin AJ: Time Spend in Non-Nursing Tasks in an Army Medical Center. Presented: AMEDD Chief Wardmaster's Conference, Denver, CO, June 1989. (C)

Frelin AJ, Staggers N, and Oda D: Role of the Clinical Nurse Specialist in the Army Medical Department. Presented: 6th Annual Research Conference, Veteran's Administration and University of Utah, Salt Lake City, Utah, February 1989. (C)

Rupkalvis C: Korean Childbirth Practices. Presented: NACOG, Armed Forces Division, San Antonio, Texas, November 1988.

#### DEPARTMENT OF PSYCHIATRY

Kolb MM: Burnout Among Physicians. Presented: Association of Military Osteopathic, Physicians & Surgeons, San Diego, Ca, March 1989.

#### DEPARTMENT OF RADIOLOGY

Haas D, Hopper K. Yakes W. Facial and Brain Trauma. Presented: Brooke Army Medical Center Academy of Health Sciences, San Antonio, TX, 1989.

Henderson R: Milligram Hours System Simplified. Presented: State-wide Meeting of Colorado Therapeutic Radiologists, Denver, CO, 1989.

Luethke J, Parker S, Haas D, Carter T: Intraoperative Ultrasound Guided Brain Biopsies Utilizing the Bard Biopsy Gun. Presented: American Roentgen Ray Society, New Orleans, LA, 1989. (C)

Parker S, Hopper K. Yakes W, et al: Image Directed Percutaneous Biopsies Utilizing the Bar Biopsy Gun. Presented: 74th Meeting of the Radiological Society of North America, Chicago, IL, November 1988. (C)

Parker S, Yakes W, Hopper K. Luethke J, Owenby J: Image-Directed Percutaneous Biopsies Using the Bard Biopsy Gun. American Roentgen Ray Society, New Orleans, LA, 1989. (C)



Sargent DW, Lepore ML, Lanier DM, Yakes WF: Sequential Preoperative Embolization of Vascular Head and Neck Tumors. Presented: American Academy of Otolaryngology and Head and Neck Surgery, New Orleans, LA, 1989.

Yakes WF, Kumpe DA, et al: Angioplasty of the Infrarenal Abdominal Aorta. Presented: 74th Meeting Radiological Society of North America, Chicago, IL, November 1988.

Yakes WF, Gibson MD, Parker SH, et al: Alcohol Embolotherapy of Vascular Malformations. 74th Meeting Radiological Society of North America, Chicago, IL, November 1988.

Yakes WF, Gibson M, Parker S: Alcohol Embolotherapy of Vascular Malformations. Presented: American Roentgen Ray Society, New Orleans, LA, May 1989.

Yakes WF: Sclerotherapy of Vascular Malformations. Presented: 14th Annual Meeting Society of Cardiovascular and Interventional Radiology, San Diego, Ca, March 1989.

Yakes WF: Angioplasty of the Infrarenal Abdominal Aorta. Presented: Annual Garry E. Wratten Symposium of Vascular Surgery, Tacoma, WA, April 1989.

Yakes WF: The Modern Neuro-Angio-Interventional Radiology Service. Presented: Annual Conference U.S. Army Medical Dept, San Antonio, TX, April 1989.

Yakes WF: State of the Art of Current Interventional Procedures. Presented: Annual Conference U.S. Army Medical Dept, San Antonio, TX, April 1989.

Yakes WF: The Gamut of PTA, and Its Importance in Clinical Practice. Presented: Medical Staff Conference McKee Medical Center, Loveland, CO, July 1989.

Yakes WF: Angioplasty of the Infrarenal Abdominal Aorta. 51st Midsummer Conference, Rocky Mountain Radiological Society, Keystone, CO, August 1989.

DEPARTMENT OF MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 79/105 (3) Status: Terminated

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(4) Title: Breathing Pattern Effects on Steady-State DLCO  
Measurement

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(5) Start Date: November 1979 (6) Est Compl Date: Indefinite

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(7) Principal Investigator: Michael E. Perry, COL, MC (8) Facility: FAMC

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(9) Dept/Svc: Medicine/Pulmonary (10) Associate Investigators:  
Neal B. Kindig, Ph.D.

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(11) Key Words:  
steady state DLCO  
breathing pattern

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_5\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

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(15) Study Objective: To experimentally confirm theoretically  
determined corrections for breathing pattern during steady-state  
diffusion studies.

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(16) Technical Approach: Breathing patterns with variations in  
inspiratory and expiratory breath-holds will be performed while the  
subject undergoes standard steady state diffusion measurement. If our  
approach is correct, mathematical corrections for breathing pattern will  
result in a constant value for diffusion capacity.

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(17) Progress: Only five patients enrolled in nine years, terminate this  
study.

Presentations:

(1) Kindig, N.B.: DLCO Correction using PaCO Back Pressure Predicted from Venous Blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO 1981.

(2) Perry, M.E.: Simplified Room Air (A-a)O<sub>2</sub> Calculation. Presented: Carl E. Temple Pulmonary Symposium, Denver, CO 1981.

Publications:

(1) Perry, M.E., Browning, R.J., Kindig, N.B.: The Abbreviated Alveolar Air Equation Revisited. Chest 80:763-764, 1981.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/120 (3) Status: Ongoing

(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis:  
Investigations into the Frequency, Type and Mechanisms  
of Carbohydrate Tolerance

(5) Start Date: 1981

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators:

(11) Key Words:  
carbohydrate  
Hyperthyroidism

T.P. O'Barr, Ph.D., DAC  
Fred D. Hofeldt, COL, (Ret)  
Robert J. Sjoberg, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 11  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance test. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach: Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 80/120

patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress: The new co-principal investigator, CPT John A. Merenich, has been analyzing the data on previous patients studied and no new patients have been entered since the last annual progress report, dated September 1988.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 81/117 (3) Status: Ongoing

(4) Title: The Role of Calcitonin in Osteoporosis

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators: Gerald S. Kidd, COL, MC

(11) Key Words:  
osteoporosis  
bone density  
calcitonin deficiency  
thyroid hormone

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 35  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if, longitudinally, thyroid cancer patients who have calcitonin deficiency and are on suppressive doses of thyroid hormone, loose radial bone more rapidly than goiter patients, who are also on suppressive doses of thyroid hormone but are not calcitonin deficient, and than normal controls. Also to compare these 3 groups, cross-sectionally, for bone density of the spine and hip.

(16) Technical Approach: 3 Groups: (a) thyroid cancer patients - calcitonin deficient and on thyroid hormone; (b) goiter patients - not calcitonin deficient but are on thyroid hormone, and (b) normal

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 81/117

controls. (SPA) single photon absorptiometry-distal and midradius serially for 5-6 yrs (in progress since 1981) (DPA) dual photon absorptiometry - spinal & hip- cross-sectionally.

(17) Progress: Thyroidectomized patients had lower bone density in the forearm in the first cross-sectional analysis but after 2 years did not lose bone at a greater rate than goiter or control patients. 6-8 year longitudinal data in the forearm and cross-sectional data in the spine and hips have been collected in most patients but the data have not yet been analyzed.

#### Publications:

McDermott MT, Kidd GS, Blue P, Ghaed V, Hofeldt FD: Reduced bone mineral content in totally thyroidectomized patients: Possible effect of calcitonin deficiency. J Clin Endocrinol Metab 56:936-9, 1983.

McDermott MT, Hofeldt F, Gidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. J Bone Min Res (1(suppl. 1):352, 1986 (Abstract).

#### Presentations:

McDermott MT, Hofeldt FD, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. Presented: 8th Annual Scientific Meeting, American Society for Bone and Mineral Research, Anaheim, CA 1986.



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 81/118 (3) Status: Ongoing

(4) Title: Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 1981

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Michael T. McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:  
Gerald S. Kidd, LTC, MC

(11) Key Words:  
hypothyroidism  
gonadal dysgenesis  
gonadotropins, pituitary

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalities resolve after treatment of the hypothyroid state.

(16) Technical Approach: A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress: No progress on new patients in the past year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 81/119 (3) Status: Ongoing

(4) Title: The Effect of Thyrotropin Releasing Hormone on Gonadotropin Releasing Hormone Stimulated Gonadotropin Secretion

(5) Start Date: 1981

(6) Est Compl Date:

(7) Principal Investigator:  
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:  
Gerald S. Kidd, LTC, MC

(11) Key Words:  
hypothyroidism  
gonadal dysgenesis

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 6  
d. Total Number of Subjects Enrolled to Date: 16  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: In order to gain a better insight into the mechanism of gonadal dysfunction in hypothyroidism, the objective of this protocol is to study the effect of a thyrotropin releasing hormone (TRH) infusion on basal and gonadotropin releasing hormone (GnRH) stimulated gonadotropins in normal subjects.

(16) Technical Approach: Sixteen normal males will be studied with either a normal saline infusion or a TRH infusion. During these infusions, GnRH will be given as a bolus with measurement of appropriate hormone to determine interaction between releasing hormones.

(17) Progress: Sixteen subjects have been studied and the data analysis is complete. The TRH infusion produced a statistically significant

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 81/119

augmentation of the FSH response (both peak and total integrated response) to GnRH, while the LH response was unaffected.

Publications: McDermott MT, Bornemann M, Sjoberg RJ, Walden T, Hofeldt F, Kidd GS: Effects of a continuous TRH infusion on GnRH stimulated gonadotropin secretion (Submitted for Publication, 1988).

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 82/104 (3) Status: Completed

(4) Title: The Effect of Tamoxifen on Gynecomastia

(5) Start Date: 1982

(6) Est Compl Date: 1989

(7) Principal Investigator:  
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:  
Fred D. Hofeldt, MD  
Gerald S. Kidd, LTC, MC

(11) Key Words:  
tamoxifen  
gynecomastia

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 12 \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this protocol is to evaluate, in a double-blind placebo controlled prospective trial, the effect of Tamoxifen on males with gynecomastia and to characterize any co-existent hormonal changes.

(16) Technical Approach: A randomized, double-blind placebo controlled study of the effects of Tamoxifen therapy on idiopathic gynecomastia will be performed. Breast size will be assessed by photographs, palpation and measurement of tissue.

(17) Progress: Six subjects have completed the study, 6 have been lost to follow-up or dropped out. Compared to placebo, Tamoxifen significantly reduced pain in all stages of the disease, but reduced size only in those with stage 3 or less.

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 82/104

Publications: McDermott MT: Tamoxifen therapy for painful gynecomastia. Endocrinology 122 (Suppl):339 (127A), 1988 (Abstract).

McDermott MT, Hofeldt FD, Kidd GS: Tamoxifen therapy for painful idiopathic gynecomastia. Submitted for publication.

Presentations: McDermott MT: Tamoxifen therapy for painful gynecomastia. Presented: 70th Meeting of the Endocrine Society, New Orleans, La, 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 82/114 (3) Status: Ongoing

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(4) Title: Growth of Basal Cell Carcinoma Cells in Defined Medium  
and Study of their Growth and Immunological  
Characteristics

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(5) Start Date: 1982

(6) Est Compl Date: 1990

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(7) Principal Investigator:  
Charles F. Ferris, MAJ, MS

(8) Facility: FAMC

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(9) Dept/Svc: DCI

(10) Associate Investigators:

Ronald W. Grimwood, MD

(11) Key Words:  
basal cell, carcinoma

J. Clark Huff, MD

Richard A.F. Clark, MC

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(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

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(15) Study Objective: Growth and study of basal cell carcinoma cells  
in cultur

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(16) Technical Approach: The approach to culturing of basal cells has,  
and will be the use of the media formulated by Dr. Ham's lab at the  
University of Colorado in Boulder termed MCDB 153. We have been  
successful to date in culturing normal cell carcinomas. This has  
included an attempt utilizing fibronectin coated plates. We next will  
be attempting growth utilizing basal cell tumors that we have success-  
fully grown in nude mice. There is experimental evidence with other  
tumors grown in nude mice to suggest that there is a greater success

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 82/114

rate of in vitro culture once the tumors have been grown in the animal model.

(17) Progress: The improved tissue culturing of keratinocytes have allowed us to begin investigating the potential growth of BCC's.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/107 (3) Status: Ongoing

(4) Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma

(5) Start Date: 1984

(6) Est Compl Date: 1992

(7) Principal Investigator:  
J. Ramsey Mellette, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators:  
John Adnot, LTC, MC  
Richard Gentry, LTC, MC

(11) Key Words:  
retinoids  
basal cell carcinoma

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 98  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Dry skin, chapped lips, myalgias.

(15) Study Objective: To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in high risk population; to examine possible side effects with long term administration of isotretinoin.

(16) Technical Approach: The study is a double-blind study with participants randomly assigned to the medication. Patients will take the med for three years and will be followed for a total of five years. Compliance side-effects and basal cells are very closely monitored.

(17) Progress: Recruitment ended on June 26, 1987. A total of 98 patients were randomized with 86 remaining on protocol. Three subjects are deceased, four transferred out of state, and five are off protocol for miscellaneous reasons. Subjects are treated with the medication for 36 months and then are followed for 2 years without medication. Four subjects are off medication and three are on dose modification.



CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 83/107

Publications:

Fitzpatrick JE, Mellette, JR: Geriatric Dermatology. In Geriatric Medicine: The Care of the Elderly Patient. First edition. W.B. Saunders Company.

Reed OM, Mellette JR, Fitzpatrick JE: Familiar Cervical Hypertrichosis with Underlying-Kypho-Scoliosis. Journal of the American Academy of Dermatology.

Presentations:

Flap Combinations for Large Facial Defects - American Academy of Dermatology Annual Meeting, San Antonio, Texas, December 1987.

Helpful Hints for Dermatological Surgery - Thirteenth Annual Tri-Services Dermatology Symposium, San Antonio, Texas.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/113 (3) Status: Ongoing

(4) Title: Growth of Human Keratinocytes

(5) Start Date: 1983

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Charles F. Ferris, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:

Ronald E. Grimwood, MD

(11) Key Words:

J. Clark Huff, MD

Phillip T. O'Barr, Ph.D., DAC

keratin

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Growth and study of human kertainocytes in culture and subsequent studies using athymicmice as an in vivo culture system.

(16) Technical Approach: The technical approach has been to grow keratinocytes obtained from newborn foreskins using serum-free media. A more successful approach has been to culture the cells in complete MCDB 153 media. A new mechanism of freezing the cells has commenced. The final phase of the study will include identifying specific proteins expressed by these cells and the presence of protein hormone receptors on the cell surfaces.

(17) Progress: Improved growth of cultures.

Publications:

Grimwood RE, Clark RAF, Baskin JB, Nielson LD, Ferris CF: Fibronectin is Deposited by Keratiocytes in the Basement Membrane Zone during Tissue Organization. Accepted for publication in Journal of Investigative Dermatology.

Grimwood RE, Ferris CF, Baskin JB, Nielson LD, Clark RAF: Fibronectin is Depostied by Keratinocytes in the Basement Membrane Zone during Tissue Organization. J. Invest. Dermatol., Vol 86, #4, 479, 1986.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/122 (3) Status: Ongoing

(4) Title: The Role of Food Allergy in the Pathogenesis of Migraine Headaches

(5) Start Date: 1983

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Thurman R. Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators:  
Teresa Copeland, CPT, MC  
David L. Goodman, LTC, MC

(11) Key Words:  
migraine  
food hypersensitivity  
mediators

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 103  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To study the value of +6 allergy food skin test in directing and defining a diet which will cause a decrease in the frequency of migraine headaches in affected patients. To determine if immunological mediators can be detected in positive responders.

(16) Technical Approach: Approximately 100 patients with dx of migraine headaches who suffered 3 or more HA/month will keep a 1 month food diary/st diary. They will then be skin tested to 83 common foods and undergo an additional 1 mo diet eliminating suspected food, and skin

test positive foods. Positive regimens will be studied with open chall. and double blind food challenge with immunologic mediators precursors.

(17) Progress: 103 patients enrolled. 37% report a 50% reduction in migraine frequency; 15 patients with positive double-blind food challenge. Five patients studied with histamine, PGD2 determinations during DBPCFC's. No problems encountered.

Presentations:

(1) Vaughan, TR, Stafford, WW, Miller, BT, Weber, RW, Tipton, WR, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: American College of Allergists, Phoenix, AZ, January 1986.

(2) Vaughan, TR, Stafford, WW, Miller, BT, Tipton, WR, Weber, RW, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: Aspen Allergy Conference, Aspen, CO, July 1986.

(3) Vaughan TR, Stafford WW, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Presented: Southwest Allergy Forum, El Paso, TX, March 1987.

(4) Vaughan TR, Stafford WS, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Accepted for presentation American College of Allergists.

(5) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double-Blind, Long-term Followup Study. Presented: VI International Food Allergy Symposium, Boston, MA., November 1987.

(6) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double Blind, Long Term Followup Study. Presented: Harold S. Nelson Allergy Symposium, Aurora, CO., January 1988.

(7) Vaughan TR: Food and Migraine Headache. Presented: Keystone Allergy Conference, Keystone, CO., February 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/126 (3) Status: Ongoing

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism

(5) Start Date: 1983 (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC  
Robert J. Sjoberg, MAJ, MC  
Gerald S. Kidd, COL, MC  
Thomas P. O'Barr, Ph.D., DAC

(9) Dept/Svc: MED/ Endocrine (10) Associate Investigators:

(11) Key Words:  
prostaglandin synthetic  
hypothyroidism  
water electrolyte balance, imbalance

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to determine in an indirect manner i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 83/126

a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: Patient recruitment has been delayed due to the investigator's other clinical and research commitments. We feel that this protocol is still of research interest and scientifically sound, and we would like to try to recruit 10-15 patients for participation within the next year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 84/100 (3) Status: Ongoing

(4) Title: The Effect of Abnormal Thyroid States on the Metabolism of Theophylline and Methylprednisolone

(5) Start Date: 1984 (6) Est Compl Date: 1988

(7) Principal Investigator: Michael T. McDermott, LTC, MC  
Ray Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:  
Stanley J. Szeffler, MD  
Harold S. Nelson, MD

(11) Key Words:  
theophylline  
methylprednisolone  
hyperthyroidism  
hypothyroidism

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 7  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine whether hyperthyroidism and hypothyroidism result in alterations of theophylline and methylprednisolone metabolism.

(16) Technical Approach: Hypo- and hyperthyroid subjects are studied when thyroid function is abnormal and again when it is normal by studying the disappearance rate of theophylline and methylprednisolone from serum after bolus injections.

(17) Progress: FT 89 - no progress since last year. 5 hyperthyroid and 2 hypothyroid patients have been studied. Theophylline metabolism is normal in hyperthyroidism and normal in hypothyroidism. Methylprednisolone metabolism is variable but essentially normal in hyper and decreased in hypothyroidism.



CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 84/100

Presentations: Lavins B, Vaughan R, Szefer S, Weber R, Nelson H:  
Effect of thyroid disease on metabolism of theophylline and  
methylprednisolone. Meetings of the American College of Allergists,  
Boston, Mass, October 1987.

Publications: None

(1) Date: 30 Sep 89 (2) Protocol #: 84/115 (3) Status: Ongoing

(4) Title: Heterotransplantation of Basal Cell Carcinomas to Nude Mice

(5) Start Date: 1984 (6) Est Compl Date: 1990

(7) Principal Investigator: Charles F. Ferris, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:  
R.E. Grimwood, MD  
J. Clark Huff, MD

(11) Key Words:  
carcinoma, basal cell  
transplantation  
mice, nude

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To develop an in-vivo model of human basal cell carcinoma in the athymic mouse.

(16) Technical Approach: Basal cell carcinoma tissue obtained from excess tissue obtained from Moh's surgery is transplanted to a subcutaneous pocket created by a linear incision on the abdomen of the nude mouse. The mouse will have been splenectomized and transplantation is followed by weekly intraperitoneal injections of antilymphocyte serum. Tumor weight is taken before implantation and measurements of tumor size taken at weekly intervals. Autoradiography and immunofluorescent studies are performed at the time of tumor harvest as well as routine histology and tumor weight.

(17) Progress: No substantive progress this year. Renewed collaboration with Dr. Grimwood is anticipated.

Presentations:

(1) Grimwood RE, Johnson CA, Kramer LC, MercillDB and Huff JC: Hetero-transplantaion of Human Basal Cell Epithelimoas in Nude Mice. Presented: SID Meeting, Washington, DC, May 1984.

(2) Grimwood, RE, Ferris CF, Nielsen LE, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude mice Produce and Deposit Fibronectin in the Extracellular Matrix. Presented: SID Meeting, Washington, DC, May 1985.

Publications:

(1) Grimwood RE, Harbel J, Clark RAF: Fibronectin in Basal cell Epitheliomas: Sources and Significance. Journal of Investigative Derm 82:145-149, 1984.

(2) Grimwood RE, Johnson CA, Ferris CF, MercillDB, Mellette JR, Huff, JC: Transplantatin of Human Basal Cell Carcinomas in Athymic Mice. Cancer

(3) Ferris, CF, Grimwood, RE, Kramer LC, Mercill DB and Huff JC: The Proliferating Cells of a Human Basal Cell Carcinoma are the Peripheal Pallisaded Cells. Abst. Clinical Research, Vol. 33, No. 2, 636A, April 1985.

(4) Grimwood RE, Ferris CF, Mercill DB and Huff JC: The Proliferating Cells of Human Basal Cell Carcinoma are Located on the Periphery of Tumor Nodules. J. Investigative Derm. Clin. Res., Vol. 33 No. 4, Page 825A.

(5) Grimwood RE, Ferris CF, Mercill DB, Huff JC: The Proliferating Cells of Human Cell Carcinoma are Locatede on the Periphery of Tumor Nodules. J. Invest. Dermatol., Vol 86, No. 2, Pg 191-194, February 1986.

(6) Grimwood RE, Ferris CF, Nielson LD, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude Mice Produce and Deposit Fibronectin in the Extracellular Matrix. J. Invest. Dermatol., 87:42-46, 1986.

(7) Grimwood RE, Siegle RJ, Ferris CF and Huff JC: The Biology of Basal Cell Carcinomas - A Revisit and Recent Developments. J. Dermatol. Surg. Oncol., 12:8, August 1986.

(8) Siegle R, Grimwood R: Athymic Mice - A Model for the Transplantation of Human Basal Cell Carcinoma. J. Dermatol. Surg. Oncol., 12:6, June 1986, pp. 646.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 84/119 (3) Status: Ongoing

(4) Title: Treatment of Graves' Ophthalmopathy with Cyclosporin

(5) Start Date: 1984

(6) Est Compl Date: 1987

(7) Principal Investigator:  
Michael T. McDermott, LTC, MC  
Leonard Wartofsky, COL, MC

(8) Facility: FAMC  
WRAMC  
MAMC  
BAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators  
Anthony Truxal, CPT, MC

(11) Key Words:  
eye disease  
cyclosporin  
prednisone

(12) Accumulative MEDCASE:\* (13) Est Accum OHA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 5  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Cyclosporine - Acne (1 pt.) Prednisone - Acne, swelling (1 pt.) Arthralgia on withdrawal (1 pt.)

(15) Study Objective: To determine the effectiveness of cyclosporin in the treatment of Graves' eye disease.

(16) Technical Approach: Patients with Graves' eye disease will receive a 3-week course of cyclosporine or prednisone, then have a 3-week rest. Then, 3 weeks of prednisone or cyclosporine (crossover). They will be followed by complete eye examination and CT scan of the orbits before and after each drug period, and twice weekly with CBC, SMA-18, urinalysis and B-2 microglobulin (urine).

(17) Progress: No new patients enlisted from FAMC in the past year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/100 (3) Status: Ongoing

(4) Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs. Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III  
SWOG #7804

(5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/102 (3) Status: Ongoing

(4) Title: Combined Modality Therapy for Breast Carcinoma, Phase III  
SWOG #7827

(5) Start Date: 1979 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/122 (3) Status: Ongoing

(4) Title: Treatment of Advanced Bladder Cancer with Preoperative  
Irradiation and Radical Cystectomy vs. Radical Cystectomy  
Alone, Phase III  
SWOG #8221

(5) Start Date: 1982 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/132 (3) Status: Ongoing

(4) Title: Evaluation of Adjuvant Therapy and Biological Parameters  
in Node Negative Operable Female Breast Cancer,  
Intergroup Study  
SWOG #8294

(5) Start Date: 1982 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 9  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/133 (3) Status: Ongoing

(4) Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation  
Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III  
SWOG #8300

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/136 (3) Status: Ongoing

(4) Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER  
Negative Stage II Carcinoma of the Breast, Phase III  
SWOG #8313

(5) Start Date: 1974 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89      (2) Protocol #: 85/139      (3) Status: Ongoing

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(4) Title: National Intergroup Protocol for Intermediate Thickness  
Melanoma 1.0-4.0 mm. Evaluation of Optimal Surgical Margins  
(2 vs 4 cm) Around the Primary Melanoma and Evaluation  
of Elective Regional Lymph Node Dissection  
SWOG #8393

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(5) Start Date: 1983      (6) Est Compl Date: Indefinite

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(7) Principal Investigator: Thomas Cosgriff, COL, MC      (8) Facility: FAMC

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(9) Dept/Svc: MED/Hema/Oncol      (10) Associate Investigators

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(11) Key Words:  
drug therapy

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(12) Accumulative MEDCASE:\*      (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

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(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/141 (3) Status: Ongoing

(4) Title: Evaluation of DTIC in Metastatic Carcinoid, Phase II  
SWOG #8411

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/142 (3) Status: Ongoing

(4) Title: Evaluation of Tamoxifen in Unresectable and Refractory  
Meningiomas, Phase II  
SWOG #8415

(5) Start Date: 1984 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89      (2) Protocol #: 85/147      (3) Status: Ongoing

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(4) Title: HLA and Gm Genes in Systemic Lupus Erythematosus  
Antibody Expression

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(5) Start Date: 1985      (6) Est Compl Date: 1988

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(7) Principal Investigator: Christopher LeSueur, MD  
Sterling West, MD      (8) Facility: FAMC

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(9) Dept/Svc: MED/Rheumatology      (10) Associate Investigators

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(11) Key Words: lupus erythematosus, systemic  
HLA antigens      Moses Shanfield, Ph.D.

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(12) Accumulative MEDCASE:\*      (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 142 \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

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(15) Study Objective: To see if patients with systemic lupus  
erythematosus have increased prevalence of any HLA and Gm genes as it  
relates to their autoantibody expression compared to a control group.

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(16) Technical Approach: After patient education and consent form is  
signed, the patient has eight tubes of heparinized blood drawn for HLA  
and Gm typing. The patient's clinical symptoms, signs and other  
laboratory parameters are collected according to protocol and correlated  
with the patient's HLA and Gm typing.

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(17) Progress: A total of 142 patients have been HLA and Gm typed. We  
have eight more patients to be HLA typed and 12 more to have Gm  
allotype. Then protocol will be completed, data analyzed and published.

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Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/157 (3) Status: Ongoing

(4) Title: Phase III Study to Determine the Effect of Combining  
Chemotherapy with Surgery and Radiotherapy for Resectable  
Squamous Cell Carcinoma of the Head and Neck  
SWOG #8590

(5) Start Date: 1985

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:  
chemotherapy

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/158 (3) Status: Ongoing

(4) Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or  
Levamisole Plus 5-Fluorouracil as Surgical Adjuvant  
Treatment for Resectable Adenocarcinoma of the Colon,  
Phase III-Intergroup  
SWOG #8591

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 2  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/163 (3) Status: Ongoing

(4) Title: The Effect of Theophylline and Nifedipine on Hormone Secretion

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators  
Gerald S. Kidd, COL, MC

(11) Key Words:  
theophylline  
nifedipine

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 10  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this protocol are to study the effect of theophylline and nifedipine on hormone secretion patterns in order to probe the intracellular mechanisms of hormone secretion and to better understand the effects of these medications on endocrine function tests.

(16) Technical Approach: Subjects will have a combined pituitary stimulation study (TRH, GnRH and ACTH) on 3 occasions: control period, during a theophylline infusion, after 2 days of taking nifedipine. Basal and peak hormone responses to the stimulating hormones will be compared among the 3 periods.

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 85/163

(17) Progress: 10 subjects have been studied. Theophylline augmented the cortisol response to ACTH and the TSH and T3 response to TRH. Nifedipine had no effect. Migraine headache occurred in one volunteer while taking nifedipine.

Publications: McDermott MT, Walden T, Bornemann M, Sjoberg RJ, Hofeldt F, Kidd GS: The effects of theophylline and nifedipine on ACTH stimulated adrenal cortisol secretion (accepted for publication).

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/165 (3) Status: Ongoing

(4) Title: An Evaluation of Cross Allergenicity Among Pollen Extracts of Members of the Chenopodiaceae and Amaranthaceae

(5) Start Date: 1985

(6) Est Compl Date: 1990

(7) Principal Investigator:  
David Goodman, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:  
pollen  
hypersensitivity  
allergens

R. Ledoux  
Bernard L. Crosby, MAJ, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate patterns of cross allergenicity among pollens of the weed families, Chenopodiaceae and Amaranthaceae.

(16) Technical Approach: Evaluation of cross reactivity using human antigen and ELISA in inhibition, rabbit antisera and CIE, CRIE. Allergen characterization using PAGE, IEF, and Western Blot.

(17) Progress: Comparison of Adjuvant Preparations. We are presently completing the immunoassays (CIE, ELISA, SDS-PAGE, and immunoblots) necessary to define quantitative and qualitative antibody production (in the rabbit model) utilizing the four adjuvant systems: Freund's adjuvant, RIBI adjuvant system, Aluminum hydroxide. Assessments of Antigenicity will be completed during the first 6 months of the calendar year 1990. These are presently under way and include SDS-PAGE and IEF separation of allergenic extract proteins, and subsequent characterization of antigenicity by crossed-immunoelectrophoretic assays. Assessments of allergenicity and cross-reactivity will similarly be completed during FY 90. Presently, we are comparing cross-reactivity utilizing a modification of the enzyme-linked immunosorbent assay system as well as utilizing nitrocellulose immunoblots to assess

specific rabbit antipollen antibody (IgG) production, and specific human antipollen antibody (IgE, IgG) production. Additionally, we are developing an enzyme-linked crossed-immunoelectrophoretic assay that may offer additional evidence of allergenic similarities amongst these weed pollen family members. This protocol using polyvalent antisera from the rabbit model will represent an important foundation step for the work of MAJ Larsen from this Service utilizing monoclonal antibodies. The delineation of the specific allergenic epitopes of these pollen families is realistically achievable.

Presentations: Goodman DL, Ledoux RA, Weber RW: Comparison of Adjuvant Systems in the Production of Pollen Antisera in Rabbits. Presented: American Academy of Allergy & Immunology Annual Meeting, Washington, DC, February 1987.

Muggleberg, ML, Ledoux RA, Weber RW: Cross-Allergenicity of Western Prairie Grasses Evaluation by ELISA Inhibition. Presented: American Academy of Allergy & Immunology, Anaheim, CA., March 1988.

Publications: Two publications expected to be completed this FY.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89      (2) Protocol #: 85/166      (3) Status: Ongoing

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(4) Title: Colon Inflammation in Reiter's Syndrome: Response to Sulfasalazine. Results in a Controlled Study

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(5) Start Date: 1985      (6) Est Compl Date: 1989

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(7) Principal Investigator:      (8) Facility: FAMC  
David Nordstrom, MD  
Sterling West, MD  
Peter Andersen, MD

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(9) Dept/Svc: MED/Rheumatology      (10) Associate Investigators

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(11) Key Words:  
Reiter's disease  
reactive arthritis

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(12) Accumulative MEDCASE:\*      (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 5  
d. Total Number of Subjects Enrolled to Date: 60  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

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(15) Study Objective: To see if patients with idiopathic Reiter's syndrome have colon inflammation and to see (in double-blinded fashion) if this responds to Sulfasalazine.

(16) Technical Approach: Colonoscopy with biopsy is performed on Reiter's patients and controls (patients with inflammatory arthritis that is not Reiter's).

(17) Progress: Patients and controls continue to be added to the protocol. Although numbers are still small, patients with Reiters seem to have a favorable response to Sulfasalazine, and their microscopic inflammation improves as well. A small number of new patients (5) have been added this FY and patients treated with Sulfasalazine continue to be followed closely for 6-8 months. A new manuscript is in preparation.

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 85/166

Publication: Nordstrom DM, West SG, Freeman S, Reddy V: HLA-B27 Positive Enterogenic Reactive Arthritis: Response of Arthritis and Microscopic Colitis to Sulfasalazine. Arthritis Rheum. 30:524, 1987.

Presentation: HLA-B27 Positive Enterogenic Reactive Arthritis: Response of Arthritis and Microscopic Colitis to Sulfasalazine. Presented: Nat. Am. Rheu. Ass., Washington, DC, July 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/167 (3) Status: Ongoing

(4) Title: The Effect of Age on Thyroid Function Studies: The  
Perchlorate Discharge Test

(5) Start Date: 1985

(6) Est Compl Date: 1989

(7) Principal Investigator:  
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators

(11) Key Words:  
thyroid diseases  
thyroid function tests  
thyroid gland

William J. Georgitis, MAJ, MC  
Michael T. McDermott, MAJ, MC  
Peter Blue, LTC, MC  
Stephen M. Manier, MAJ, MC  
Tony L. Walden, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_1\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_11\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the  
effect of age on the perchlorate discharge test in individuals with  
thyroid disease.

(16) Technical Approach: Patients over the age of 60 years without  
thyroid disease by history, physical examination and lab evaluation will  
be studied. A perchlorate test will be performed in Nuclear Medicine.

17) Progress: One new patient was studied during FY 88 without  
complications or difficulties.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 85/174 (3) Status: Ongoing

(4) Title: Evaluation of Combination Chemotherapy Using High Dose  
ARA-C in Adult Acute Leukemia and Chronic Granulocytic  
Leukemia in Blastic Crisis, Phase III  
SWOG 8326/27

(5) Start Date: 1983 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/10X-001 (3) Status: Ongoing

(4) Title: Feasibility Study to Determine if Estrogen and Progesterone Affect in-vitro Growth of Cultured Malignant Melanoma (MM) Cell Lines

(5) Start Date: 1986

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Charles F. Ferris, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: MED/Dermatology

(10) Associate Investigators

Donald B. Mercill, DAC

(11) Key Words:  
malignant melanoma  
receptors  
estrogen  
progesterone

Thomas P. O'Barr, DAC

Charles F. Ferris, CPT, MS

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether malignant melanoma cell lines previously obtained and stored (frozen) have estrogen and progesterone receptors. If receptors can be identified, then a full scale protocol can be undertaken to determine if estrogen and progesterone have an effect on cell growth.

(16) Technical Approach: Malignant melanoma cells lines currently stored in the Cell Physiology Service will be grown to confluence. Specific binding will be characterized utilizing a dextran-coated charcoal technique.

(17) Progress: Control receptor analysis is completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/100 (3) Status: Terminated

(4) Title: Assessment of Nonspecific Decrease in Skin Test Reactivity  
During Immunotherapy

(5) Start Date: 1986

(6) Est Compl Date: 1989

(7) Principal Investigator:  
Richard W. Weber, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators  
James S. Brown, LTC, MC  
Bernard L. Crosby, MAJ, MC

(11) Key Words:  
skin test  
immunotherapy

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 6  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether there is a nonspecific decrease in skin test reactivity to unrelated extracts during immunotherapy.

(16) Technical Approach: Patients placed on immunotherapy will receive periodic titrated skin tests to allergens in the treatment sets, as well as allergens not in the treatment sets, as well as skin tests to histamine and compound 48/80.

(17) Progress: In progress, active, 5 are completed. Protocol terminated as PI retired. Elements of this have been incorporated in a larger protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/103 (3) Status: Ongoing

(4) Title: Evaluation of Low Dose Ara-C versus Supportive Therapy  
Alone in the Treatment of Myelodysplastic Syndromes  
(ECOG EST 4483)  
SWOG #8592

(5) Start Date: 1985 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of  
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/107 (3) Status: Ongoing

(4) Title: In-Vitro Drug Sensitivity Utilizing the Guinea Pig Airway  
Smooth Muscle Model

(5) Start Date: 1986

(6) Est Compl Date: 1991

(7) Principal Investigator:  
T. Ray Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators

(11) Key Words:  
drug sensitivity

Anthony R. Henry, LTC, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 47  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: We have previously demonstrated in the guinea pig  
tracheal model the development of subsensitivity to beta-adrenergic  
agonists. It would now be useful to have an animal model in which we  
can safely study the pharmacodynamic interactions involved in beta-  
adrenergic blocker induced bronchoconstriction. Specifically, it will  
be important to determine the direct effects of beta-adrenergic blockers  
on tracheal smooth muscle prior to histamine-induced tracheal  
constriction. Then, it will be important to determine the effects of  
beta-adrenergic agonists and anticholinergics on beta-adrenergic blocker  
induced tracheal constriction.

(16) Technical Approach: In-vitro blockade of beta-adrenergic receptors of the guinea pig trachea will be achieved after the guinea pig tracheas have been excised, divided into segments, and placed into tissue chambers under physiologic conditions. Subsequently, the effects of beta-adrenergic blockers will be studied before and after the induction of tracheal smooth muscle contraction by histamine. Finally, the effects of beta-adrenergic agonists and anticholinergics on the beta-adrenergic blocker induced tracheal smooth muscle constriction will be studied.

(17) Progress: (a) Propranolol ( $10^{-4}M$ ) causes no significant tracheal smooth muscle contraction. (b) Pretreatment with propranolol potentiates histamine-induced tracheal smooth muscle contraction. (c) Pretreatment with propranolol attenuates albuterol reversal of histamine-induced smooth muscle contraction. (d) We have established an in-vitro model with which we can safely study the pharmacodynamic interactions involved in beta-blocker potentiated bronchoconstriction. (e) Atropine methylnitrate causes no significant reversal of the histamine-induced tracheal smooth muscle contraction during the observation period (5-10 minutes). (f) Atropine sulfate causes reversal of the histamine-induced tracheal smooth muscle contraction. (g) Propranolol ( $10^{-6}M$ ) causes no significant tracheal smooth muscle contraction. (h) Pretreatment with propranolol ( $10^{-6}M$ ) appears to potentiate histamine-induced tracheal smooth muscle contraction. (i) Both g & h are important because of  $10^{-6}M$  propranolol reflects reported tissue concentrations of propranolol in the lung.

Presentations: American College of Allergist National Meeting, 1986; Hugh Mahon Lectureship Award Competition (1st place award in lab category and grand prize award) FAMC, 1989. Aspen Allergy Conference Regional Meeting, 1989. American College of Allergy & Immunology National Meeting, 1989.

Publications: Ann. All. 56:117-119, 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/108 (3) Status: Completed

(4) Title: Investigation of Alterations in Angiotensin Converting Enzyme Activities Resulting from Different Prolactinemic States in the Male Sprague-Dawley Rat

(5) Start Date: 1986

(6) Est Compl Date: FY 87

(7) Principal Investigator:  
William J. Georgitis, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators  
Gerald S. Kidd, COL, MC  
Tony L. Walden, CPT, MC  
Lawrence E. Jones, DAC  
Charles F. Ferris, CPT, MS  
Ellen Swanson, DAC  
Sharon Noble, DAC  
Arnold Asp, MAJ, MC

(11) Key Words:  
angiotensins  
prolactinemic states

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 7 Jan 86 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: 60 rats  
d. Total Number of Subjects Enrolled to Date: 60 rats  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: This experiment is designed to investigate whether the activity of angiotensin converting enzyme in male Sprague-Dawley rats is altered by prolactin.

(16) Technical Approach: Four groups of rats were treated with vehicle, pergolide, metoclopramide, and metoclopramide plus testosterone delivered by Alzet osmotic minipumps for two weeks.

(17) Progress: No one treatment effect was achieved but hastene perimeters of gonadal were unaltered by the different states of prolactin achieved by the drugs.

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 86/108

Publications:

(1) Georgitis W., Asp., Swanson E., Noble S., and Kidd G: Angiotensin Converting Enzyme Activity in Different Prolactinemic States. (Abstract) Clinical Res. 35(1):119A, 1987.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/109 (3) Status: Ongoing

(4) Title: The Effect of INH and Combination INH-Rifampin Therapy on Calcium and Vitamin D Metabolism

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:  
John Merenich, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators

Gerald S. Kidd, LTC, MC

Michael E. Perry, COL, MC

Michael T. McDermott, MAJ, MC

Fred Negron, CPT, MC

Peter Blue, LTC, MC

Nasser Ghaed, COL, MC

(11) Key Words:  
calcium  
vitamin D rifampin  
vitamin D deficiency

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 7 \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The purpose of this study is to see if INH therapy alters vitamin D and/or calcium metabolism in a significant manner. This may then lead to further evaluation to determine if patients would benefit from vit D or calcium supplementation while receiving INH therapy.

(16) Technical Approach: Ten to 20 patients will be begun on INH therapy for their recent PPD conversion. Determinations of Vit D (25-OH, 1,25-OH), serum calcium, PTH, 24-hour urine calcium and SMA-18 are drawn at baseline, 2 weeks, 6 and 9 months. Bone densitometry is obtained before and after therapy.

(17) Progress: Seven patients have been entered in the study as of this date. I have re-established ties with the pulmonary department, I have also contacted Dr. Asp to examine the feasibility of conducting the protocol at his institution. I hope to be enrolling new patients soon

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/114 (3) Status: Ongoing

(4) Title: Natural History of HTLV-III Infection and Disease in a  
United States Military Community

(5) Start Date: 1986

(6) Est Compl Date: 1992

(7) Principal Investigator:  
Shannon M. Harrison, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators

Leo A. Andron, LTC, MC

(11) Key Words:  
HIV virus

Roland N. Hannon, PA-C, CW3 (RET)

Richard W. Burris, PA-C, GS12

Robert H. Gates, MAJ, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 11/88 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: 100  
d. Total Number of Subjects Enrolled to Date: 400  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e". None

(15) Study Objective: To develop an accurate, thorough understanding of  
the pattern of disease progression and clinical course in individuals  
with documented HTLV-III infection within the general military  
population including active duty, dependents, and retirees. This will  
provide critical information for clinical and administrative management  
of patients.

(16) Technical Approach: Collect data on all patients who are required  
to be staged by DA directives and any who request staging.

(17) Progress: No changes except as noted for amendments in the  
protocol.

Publications and Presentations: None

(1) Date: 30 Sep 89 (2) Protocol #: 86/115 (3) Status: Terminated

(4) Title: A Prospective Evaluation of Neuropsychiatric Sequelae  
of HTLV-III Disease

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:  
William Clayton, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: of Medicine

(10) Associate Investigators

Shannon M. Harrison, LTC, MC

(11) Key Words:  
human immunodeficiency virus  
neuropsychological tests

Richard G. Grape, SSG, USA

Leo A. Andron, LTC, MS

Rowland N. Hannon, PA-C CW3 RET

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 44

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the prevalence and progression of neuropsychiatric disease in an HTLV-III positive military population.

(16) Technical Approach: Patients have been enrolled in the Neuropsychiatric Protocol from the umbrella Protocol dealing with Natural History of HTLV-III Disease. This allocation has been random except for expectation of good follow up. There have been no significant changes in overall protocol approach.

(17) Progress: Twenty-four individuals have been lost to follow-up due to separation from the service. Eleven patients were removed from the study and placed on AZT protocol. Three patients died within 6 months of entering the study. It is felt at this time that due to the high attrition rate, the study should be discontinued.

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 86/115

**Presentations:**

Haburchak, D.R.: A Prospective Evaluation of Neuropsychiatric Sequelae of HTLV-III Disease. Presented: U.S. Army AIDS Conference, Arlington, VA, September 1986.

Haburchak D, Harrison S, Andron L, Grape R, Hannon R, Clayton W: Neuropsychologic Evaluation of HIV Seropositive U.S. Army Soldiers. Fitzsimons Army Medical Center.

**Publications:** None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/116 (3) Status: Completed

(4) Title: Endocrine Function in the Acquired Immune Deficiency Syndrome

(5) Start Date: 1986 (6) Est Compl Date: July 1987

(7) Principal Investigator: John Merenich, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators  
Gerald S. Kidd, LTC, MC  
(11) Key Words: M. McDermott, LTC, MC  
acquired immunodeficiency A. Asp, CPT, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 46 subjects; 19 controls  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this study are to detect, define, and determine the incidence of abnormalities of the pituitary gland, adrenal gland, thyroid gland and gonads in patients with acquired immune deficiency syndrome and its variants.

(16) Technical Approach: Patients who are detected as being positive for HTLV III are staged and then endocrine function is studied with a combined pituitary test consisting of the intravenous injection of ACTH, TRH and GnRH with subsequent measurement over the next 3 hours for cortisol, aldosterone, TRH, T4, T3, FSH and LH.

(17) Progress: Completed

Presentations:

2 presentations/publications as abstracts  
Submitted for journal publication

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 86/118 (3) Status: Ongoing

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(4) Title: Maintenance vs. No Maintenance BCG Immunotherapy of  
Superficial Bladder Cancer  
SWOG #8507

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(5) Start Date: 1985 (6) Est Compl Date: Indefinite

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(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

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(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

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(11) Key Words:  
chemotherapy

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

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(15) Study Objective: To participate in the SWOG group in the study of  
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/119 (3) Status: Ongoing

(4) Title: Randomized Comparison of Cisplatin + 5-Fluorouracil vs.  
CBDCA + 5-Fluorouracil vs. Methotrexate in Advanced  
Squamous Cell Carcinoma of the Head and Neck, Phase III  
SWOG #8514

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of  
adult oncological malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/120 (3) Status: Ongoing

(4) Title: A Phase II Comparison of CHOP versus m-BACOD versus  
ProMaCE-CytaBOM versus MACOP-B in Patients with  
Intermediate or High Grade Non-Hodgkin's Lymphoma  
SWOG #8516

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 2  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of  
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/122 (3) Status: Terminated

(4) Title: Pulmonary Function Standards at FAMC: Correlation with Anthropomorphic Measurement

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:  
Michael E. Perry, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary

(10) Associate Investigators

(11) Key Words:  
anthropometry  
pulmonary gas exchange

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 19  
d. Total Number of Subjects Enrolled to Date: 70  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the spirometry, body plethysmography and diffusion capacity normal standards for Fitzsimons Army Medical Center.

(16) Technical Approach: As pointed out in original protocol, non smoking volunteers undergo spirometry, body plethysmography DLCO, at the PFT lab, chest measurements/height/weight recorded and this data included for regression analysis and assess any correlation.

(17) Progress: Severe staffing shortages prevent work on this protocol.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 86/123 (3) Status: Ongoing

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(4) Title: Phase II Evaluation of Methyl-Glyoxal Bis-Guanylhydrazone  
(MGBG) in Patients with Advanced Bladder Cancer  
SWOG #8519

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(5) Start Date: (6) Est Compl Date:

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(7) Principal Investigator: (8) Facility: FAMC  
Thomas Cosgriff, COL, MC

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(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

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(11) Key Words:  
drug therapy

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

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(15) Study Objective: To participate in the SWOG group in the study of  
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 86/124 (3) Status: Ongoing

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(4) Title: Treatment of Limited Small Cell Lung Cancer with Concurrent  
Chemotherapy, Radiotherapy and Intensification with High  
Dose Cyclophosphamide  
SWOG #8573

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(5) Start Date: 1985 (6) Est Compl Date: Indefinite

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(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

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(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

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(11) Key Words:  
drug therapy

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

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(15) Study Objective: To participate in the SWOG group in the study of  
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continues to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/125 (3) Status: Completed

(4) Title: A Randomized Comparative Trial of Lobectomy versus Limited  
Resection for Patients with Cancer of the Lung  
LCSG #821

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Daniel Tell, LTC, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Completed

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 86/126 (3) Status: Ongoing

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(4) Title: A Prospective Randomized Trial to Determine the Benefit  
of Surgical Resection of Residual Disease Following  
Response of Small Cell Lung Cancer to Combination  
Chemotherapy  
LCSG #832

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(5) Start Date: (6) Est Compl Date:

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(7) Principal Investigator: (8) Facility: FAMC  
Thomas Cosgriff, COL, MC

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(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

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(11) Key Words:  
drug therapy

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 1  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

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(15) Study Objective: To participate in the LCSG group protocols.

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(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/128 (3) Status: Ongoing

(4) Title: A Clinical Trial in Patients with Stage II and III  
Completely Resected Non-Small Cancer of the Lung  
Comparing Chemotherapy vs. No Therapy Following  
Surgery  
LCSG #853

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the LCSG group protocols.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/129 (3) Status: Completed

(4) Title: Evaluation of Ambulatory Recording Oximetry and  
Holter Monitoring in Screening for Sleep Apnea

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: Gary L. Jackson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary Dis. (10) Associate Investigators  
Jean Foucauld, CPT, MC  
Michael Perry, COL, MC

(11) Key Words:  
oximetry  
sleep apnea syndromes

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 6  
d. Total Number of Subjects Enrolled to Date: 28  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To investigate a cost saving method to screen  
clinically suspected sleep apnea patients with a non-invasive recording  
pulse oximeter measuring oxyhemoglobin desaturation. No medications  
will be used. Patients will be seen and evaluated for SAS by the  
Pulmonary Disease Service.

(16) Technical Approach: Patients are selected on the basis of  
clinically suspected sleep apnea. Patients are then screened with  
overnight recording pulse oximetry and studied with holter monitoring  
simultaneously. Within 24 hours the patients are then studied with a  
formal sleep study to validate the findings in a positive predictive  
manner.

(17) Progress: The screening study has been ongoing and is current with  
respect to data collection and assessment. An abstract was accepted by  
AM Thoracic Society for publication Apr 88 with the patient number as

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above, we cannot show a spearman rank differential correlation between screening and formal SAS studies. In the study design, the best evaluation of patients occurs without esophageal balloons in the formal overnight studies.

Presentations: American College of Physicians USA Regional Meeting, San Francisco, CA., October 1987. Abstract accepted by American Thoracic Society, Las Vegas, Nevada, April, 1988.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/132A (3) Status: Ongoing

(4) Title: The Effect of Theophylline on Calcium and Vitamin D  
Metabolism in Male Sprague-Dawley Rats

(5) Start Date: (6) Est Compl Date: 1988

(7) Principal Investigator: (8) Facility: FAMC  
Edwin J. Fortenberry, CPT, MC  
Michael T. McDermott, MAJ, MC

(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators  
Gerald S. Kidd, COL, MC

(11) Key Words:  
theophylline  
vitamin D  
calcium

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 49 male rats  
d. Total Number of Subjects Enrolled to Date: 49 male rats  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of the study are to determine the effect of chronic theophylline administration on calcium and Vitamin D metabolism and bone mineral content in rats.

(16) Technical Approach: Theophylline (n=25) or saline (n=24) are administered by continuous infusion with an Alzet osmotic pump for a period of 4 weeks. After 2 1/2 weeks, measurements are made of 24 hour calcium intake, urine calcium, and fecal calcium excretion and overall calcium balance is calculated. After 4 weeks, the rats are sacrificed and serum calcium PTH, 25 (OH) Vitamin D and 1,25 (OH)<sub>2</sub> vitamin D are measured. The rats are ashed for determination of total body calcium.



(17) Progress: Theophylline treated rats (n=25) had significantly greater urinary calcium excretion and significantly lower 25(OH) Vitamin D levels than did control rats (n=24). They also had slightly lower 1,25 (OH)<sub>2</sub> vitamin D levels and total body calcium per gram of body weight. PTH levels are pending.

**Presentations:**

(1) McDermott MT, Fortenbery EJ, Duncan WE. Theophylline alters vitamin D and calcium metabolism in rats. 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

**Publications:**

(1) McDermott MT, Fortenbery EJ, Duncan WE: Theophylline alters vitamin D and calcium metabolism in rats. J Bone Min Res 3(Suppl. 1): 5115 (188A)

(2) Fortenbery EJ, McDermott MT, Duncan WE: The effect of theophylline on calcium and vitamin D metabolism. J. Bone Min. Res. Cln. Press.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/102 (3) Status: Ongoing

(4) Title: Anti-Histone Antibody Production in Procainamide Associated  
Drug-Induced Lupus Erythematosus: Association of Serologic  
Patterns and Lymphocyte Subsets

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: James D. Singleton, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology (10) Associate Investigators  
Peter A. Andersen, LTC, MC  
West, Sterling, LTC, MC

(11) Key Words:  
procainamide  
drug-induced lupus  
histones

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 19  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None

(15) Study Objective: There are two study objectives: a) to survey the  
population of patients receiving procainamide to determine baseline data  
and b) to evaluate a subgroup of patients chosen randomly from patient  
populations determined by amount of drug administered, serologic status,  
and the presence of symptomatology.

(16) Technical Approach: Autoantibodies are one of the hallmarks of SLE  
yet mechanisms of their production and their pathogenetic import remain  
unclear. Drug-induced lupus makes feasible the investigation of poten-  
tial early immunologic abnormalities which would lead to autoantibody  
production. Demographic, clinical and serologic data will be obtained  
on patients taking procainamide. Selected patients will, additionally,  
have T-cell and B-cell lymphocyte studies and be followed serially to

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 87/102

discover correlates, if any, in studied parameters.

(17) Progress: Although only 19 patients have been enrolled in the study and baseline data obtained, approximately 110 individuals receiving procainamide have been identified. Efforts to contact these, obtain informed consent and finally enroll them in the study are ongoing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/103 (3) Status: Ongoing

(4) Title: Identification of Those at Risk for Osteoporotic Hip Fractures, by a Noninvasive Measurement

(5) Start Date: Jan 87 (6) Est Compl Date: 1989

(7) Principal Investigator: Jan J. Perloff, CPT, MC  
Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology (10) Associate Investigators

(11) Key Words: osteoporosis hip fractures Gerald S. Kidd, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 25  
d. Total Number of Subjects Enrolled to Date: 70  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To evaluate possible risk factors for osteoporosis by comparing hip fracture patients and matched controls for bone density, calcium intake, smoking, medications, mental status, visual acuity, vitamin D levels and exercise history.

(16) Technical Approach: Hip fracture patients, within 5 days of fracture, and normal matched controls will have measurement of bone density at 3 sites in the unaffected hip and in the spine by dual photon ab-

sorptiometry and in the non-dominant midradius by single photon absorptiometry. All subjects will have a history and physical examination to include dietary and exercise history. Twenty subjects from each group will have visual acuity and 25-hydroxy vitamin D levels evaluated.

(17) Progress: Patients with hip fractures had significantly reduced bone density in the hip and lumbar spine and significantly lower calcium intakes.

Presentations:

(1) McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. Presented: 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

Publications:

(1) Perloff JJ, McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. J Bone Min Res 3(Suppl. 1):587(73A), 1988, (Abstract).

(2) Perloff JJ, McDermott MT, Perloff KG, Blue PW, Enzenhauer R, Seik E, Chantelois A, Dolbow A, Kidd GS: Risk factors for osteoporotic hip fractures (Submitted for publication).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/104 (3) Status: Ongoing

(4) Title: A Randomized Investiation of High-Dose Versus Standard  
Dose Cytosine Abarinoside with Daunorubicin in Patients  
with Acute Non-Lymphocytic Leukemia, Phase III  
SWOG 8600

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group  
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/105 (3) Status: Ongoing

(4) Title: Pre-operative Cimetidine Therapy in Patients Undergoing Parathyroid Exploration: Efficacy and Mechanisms of Action

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
John A. Merenich CPT, MC  
Jeffrey R. Clark, COL, MC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators  
Michael T. McDermott, MC  
William J. Georgitis, MAJ, MC  
(11) Key Words: hyperparathyroidism Arnold A. Asp, MAJ, MC  
postoperative hypocalcemia Gerald S. Kidd, COL, MC

Accumulative MEDCASE:\* (12) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 21  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".----Last year one patient developed moderate elevations of liver function tests. She was completely asymptomatic, but her parathyroid surgery was postponed (until her tests returned to normal) and she was dropped from the study. She has subsequently undergone surgery without complications and LFT's remain normal. This year, none of the new patients experienced any complications.

(15) Study Objective: To determine whether or not pre-operative cimetidine therapy can reduce the incidence of post-operative hypocalcemia in patients undergoing parathyroid explorative surgery.

(16) Technical Approach: Patients are given placebo or cimetidine for 10 days prior to their surgery in a double-blind fashion. Calcium and its regulatory hormones are monitored before and after surgery to see if cimetidine favorably alters calcium homeostasis.

(17) Progress: Continuing to get patients. Anticipate completion within six months, all but one subject undergoing parathyroid.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/106 (3) Status: Terminated

(4) Title: Effect of Concomitant Alcohol and Exercise on High Density Lipoprotein Subfractions and Lipolytic Enzymes in Sedentary, Healthy Men

(5) Start Date: 1987 (6) Est Compl Date: 1988

(7) Principal Investigator: Kerry C. Prewitt, CPT, MC  
John A. Merenich, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators  
William Georgitis, MAJ, MC  
Robert Eckel, MD  
Gerald S. Kidd, COL, MC

(11) Key Words:  
alcohol  
lipoproteins  
apolipoproteins  
lipase

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 14  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine the effects of alcohol alone and in conjunction with exercise on lipid status (and the enzymes that control lipids) in healthy men.

(16) Technical Approach: Participants asked to completely abstain from alcohol or to drink alcohol at social levels while activity levels are manipulated. Lipids and lipoprotein activities are determined before and after these manipulations to assess their effect.

(17) Progress: Terminated due to lack of volunteers.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/110 (3) Status: Completed

(4) Title: The Role of Excess Prostaglandin Production in Causing  
The Abnormal Hemodynamic Status of Adrenalectomized Rats

(5) Start Date: 1987 (6) Est Compl Date: 1989

(7) Principal Investigator: Robert J. Sjoberg, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators

John Merenich CPT, MC  
Gerald S. Kidd, COL, MC  
T.P. O'Barr, DAC

(11) Key Words:  
prostaglandins  
adrenal insufficiency

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To clarify the role of altered renal and arterial  
prostaglandin production in mediating the hemodynamic alterations as-  
sociated with adrenal insufficiency.

(16) Technical Approach: The approach used involved investigations of  
(a) comparison of the physiologic response of adrenalectomized rats to  
prostaglandin synthesis inhibitors and to glucocorticoid replacement and  
b) the ex vivo elaboration of prostaglandins by renal and arterial  
tissue taken from adrenalectomized rats.

(17) Progress: Because of limited time devoted to animal research, we  
have decided to submit a manuscript regarding the results of the initial  
protocol to a referee journal in order to obtain comments regarding the  
initial data in hopes of directing follow up studies in the appropriate  
manner .

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT    Protocol #: 87/110

Presentations: Sjoberg R, Merenich J, O'Barr, Kidd G: Renal and arterial prostaglandin production in insufficiency. (Abstract) Presented: 70th Annual Meeting of the Endocrine Society, New Orleans, La, 1988.

Publications: Accepted (pending revisions) to Journal Laboratory and Clinical Sciences

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 87/111 (3) Status: Ongoing

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(4) Title: A Prospective Double Blind Study of Zidovudine in Early HIV Infection

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(5) Start Date: 31 Oct 87 (6) Est Compl Date: 1991, Feb

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(7) Principal Investigator: Shannon Harrison, LTC, MC (8) Facility: FAMC Denver Health & Hospitals

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(9) Dept/Svc: DCI (10) Associate Investigators

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(11) Key Words: ZOV asymptomatic HIV R.N. Hannon, PA-C Leo Andron, LTC, MS Robert H. Gates, MAJ, MC

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report. (Fenced HSC/HIV monies & P6 MED R&D Grant renewed for FY 90 & 91)

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(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 66 FAMC/212 DH&H  
d. Total Number of Subjects Enrolled to Date: 66 & 212  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". (1 RBC aplasia; 4 granulocytopenia; 6 thrombocytopenia; 1 severe nausea and vomiting; none off study).

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(15) Study Objective: To look for efficacy and toxicity in terms of difference in natural history of Walter Reed Stage II through early V, HIV infected individuals given zidovudine at 200mg every 6 hours vs placebo.

(16) Technical Approach: 17 study endpoints/53 withdrawals: misentries, no toxicity.

(17) Progress: Protocol was closed 1 February 1989.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/112 (3) Status: Ongoing

(4) Title: (RTOG-85-01) Prospective Trial for Localized Cancer of The Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup  
SWOG-8598

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: In progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/113 (3) Status: Ongoing

(4) Title: A Phase II Randomized Trial of Combination Therapy for Multiple Myeloma: Comparison of (1) VMCP/VBAP to VAD or VMCP/VBAPP for Induction, (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha -2b Interferon + Dexamethasone for Incomplete or Nonresponders

SWOG 8624

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words: drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Protocol ongoing.

Publications and Presentations: None



CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 87/114

Publications:

Weaver MJ, Ow CL, Walker DJ and Degenhardt EF: Evaluation of Residents Humanistic Qualities by Patients and Attending Physicians (Abstract Submitted)

Presentations:

Ow C, Weaver M, Walker D, Degenhardt E: Patient Evaluation of Physicians Humanistic Qualities. (Accepted for presentation at Army Regional LAP meeting, October 1989).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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- (1) Date: 30 Sep 89      (2) Protocol #: 87/115      (3) Status: Ongoing
- 
- (4) Title: Double Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock
- 
- (5) Start Date:      (6) Est Compl Date: 1990
- 
- (7) Principal Investigator: Richard Winn, LTC, USAF, MC      (8) Facility: FAMC
- 
- (9) Dept/Svc: MED/Pul Dis Svc.      (10) Associate Investigators  
Shannon M. Harrison, LTC, MC  
Robert H. Gates, MAJ, MC
- 
- (11) Key Words:  
gram negative shock  
gram negative spesis  
monoclonal antibody  
HA-1A monoclonal antibody
- 
- (12) Accumulative MEDCASE:\*      (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.
- 
- (14) a. Date, Latest IRC Review:      b. Review Results:      c. Number of Subjects Enrolled During Reporting Period:      d. Total Number of Subjects Enrolled to Date: 4      e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- 
- (15) Objective: To determine the efficacy of HA-1A monoclonal antibody in reducing the mortality and/or direct morbidity of gram-negative sepsis as compared to a placebo treated control group. To determine the impact that HA-1A has on patient benefit. To determine the impact that HA-1A has on laboratory parameters/clinical signs associated with sepsis. To determine the safety and potential for immunogenicity of HA-1A monoclonal antibody administration in patients presenting with clinical syndrome of gram-negative sepsis.
- 
- (16) Technical Approach: Patients with the clinical diagnosis of septic shock or sepsis suspected of being secondary to gram-negative organisms will be treated with one dose of either placebo or HA-1A monoclonal antibody. A comparison of morbidity and mortality between the placebo and HA-1A group will be made to determine efficacy and safety of the drug.
- 
- (17) Progress: Enrollment of patients at FAMC is complete. Additional study on specimens and samples will be performed.
- 
- Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/116 (3) Status: Ongoing

(4) Title: Effect of Iodine Containing Water Purification Tablets  
on Thyroid Function in Man

(5) Start Date: Aug 87

(6) Est Compl Date:

(7) Principal Investigator:  
Michael T. McDermott, LTC, MC  
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators

(11) Key Words:  
iodine  
water purification tablets  
thyroid function tests

John R. Barrett, LTC, MC  
William J. Georgitis, LTC, MC  
Robert J. Sjoberg, MAJ, MC  
John A. Merenich, CPT, MC  
Kenneth Simcic, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 14  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this study are to investigate  
the effects of iodine containing water purification tablets on thyroid  
function and job performance in soldiers in a field environment.

(16) Technical Approach: See Protocol

(17) Progress: Seven subjects taking iodine and 7 controls not taking  
iodine have completed the study in a military field training setting.  
Controls had no changes in thyroid function or basal or TRH stimulated  
TSH levels. Study subjects taking iodine water purification tablets had  
statistically significant reductions in T4 and T3 and increments in  
basal and TRH stimulated TSH levels.

**Presentations:**

Georgitis WJ, McDermott MT: Iodine water purification tablets alter  
thyroid function in man. Presented: 71st Meeting of the Endocrine  
Society, Seattle, WA. Endocrinology 124(Suppl):480 (1830A), 1989.

**Publications:** None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/117 (3) Status: Ongoing

(4) Title: Analysis of von Willebrand Factor Multimers Before  
and After Cardiopulmonary Bypass

(5) Start Date: 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: B. Vishnu V. Reddy, LTC, M<sup>C</sup> (8) Facility: FAMC

(9) Dept/Svc: Pathology (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 25  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the effect of the cardiopulmonary bypass machine on the multimeric structure of von Willebrand's factor and to provide clinical research experience for FAMC residents and staff.

(16) Technical Approach: See Protocol

(17) Progress: No results are available due to technical problems with electrophoresis set up.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/101 (3) Status: Ongoing

(4) Title: Centralized Non-Small Cell Lung Cancer Specimen  
Repository and DNA/RNA Bank  
LCSG 871

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hemo/Oncol Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 22  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the LCSG group protocol.

(16) Technical Approach: See protocol.

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/102 (3) Status: Ongoing

(4) Title: Effect of Chronic Coumadin Therapy on Cortical and Trabecular Bone Density in Man

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Michael McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc. (10) Associate Investigators  
Gerald S. Kidd, COL, MC  
Peter Blue, LTC, MC

(11) Key Words:  
bone density  
coumadin  
osteocalcin

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 20  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to investigate the bone density of cortical and trabecular bone in patients on chronic coumadin therapy and in age-matched controls.

(16) Technical Approach: See protocol.

(17) Progress: Coumadin patients do not have lower bone density than matched controls.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/103 (3) Status: Ongoing

(4) Title: Clinical Efficacy of Phenindamine as Determined  
by Skin Test Suppression

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Thurman R. Vaughan, MAJ, MC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators  
Edward W. Green COL, MC  
Paul R. Sklarew, CPT, MC

(11) Key Words:  
antihistamine  
phenindamine

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To examine the null hypotheses that there is no difference in skin test suppression and side effects produced by phenindamine 25mg qid, chlorpheniramine 8mg tid, and placebo in 2 week trials in normal subjects.

(16) Technical Approach: Twenty subjects will take part in a placebo controlled crossover study of the skin test suppression produced by phenindamine, chlorpheniramine, and placebo. Results will be used to evaluate the efficacy, as determined by skin test suppression, of phenindamine compared to chlorpheniramine and placebo.

(17) Progress: No patients have entered to date. Investigators are now available. However, as phenindamine is being marketed as a non-sedating antihistamine, we feel the more appropriate comparison would be with terfenadine (seldane). An amendment to this protocol is being prepared.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/104 (3) Status: Ongoing

(4) Title: A Descriptive Study of Pastoral Care Interventions Designed to Assist HIV+/AIDS Patients in Achieving Their Maximum Quality of Life

(5) Start Date:

(6) Est Compl Date: 1990

(7) Principal Investigator:  
F. William Miles, LTC, USAR  
(Chaplain)

(8) Facility: FAMC

(9) Dept/Svc: Minis. & Past. Care

(10) Associate Investigators  
Shannon M. Harrison, LTC, MC  
Robert L. Campbell (CH), COL  
Jerry Webb, COL (CH)  
Robert H. Gates, LTC, MC  
Ray Logan, MAJ, (CH), Ft. Carson

(11) Key Words:  
psycho-social-spiritual  
cognitive, moral and  
faith development

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: Tst/157/Intr/36  
d. Total Number of Subjects Enrolled to Date: Tst/332/Intr95  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective: (a) To observe and document the continuity of pastoral care with a traumatically stressed patient population (FAMC and beyond). (b) To conduct a longitudinal descriptive study that shows process from the point of view of patient, family member, supervisor and pastoral care giver. (c) To encourage personal processing of issues that impact on a sense of well being, decision making, psycho-social-spiritual growth through the use of an intentional and prescribed series of pastoral interventions. To provide the patient personal gain from telling his/her own "story." (d) To look at life histories, values, moral/faith development, personality types as they inform the pastoral care giver for ministry.

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(16) Technical Approach: We are developing a pastoral data base of information relative to providing pastoral care to HIV+/AIDS patients. This is accomplished through regular personality inventories and interviews every six months during the HIV staging process, as well as follow-up questionnaires and support visits/calls to determine continuity of pastoral care and individuals functioning at unit/home.

(17) Progress: The protocol is still in the data gathering phase. We intend to cut off new data gathering, except for followup testing and interviews, and prisoners and women, by 30 Dec 89. Coordination has been in process with Staff Chaplains at HSC, FORSCOM, and Ft. Carson to obtain a control group, a random sample of soldiers by age, MOS, and rank, with whom to compare our patient group.

Publications:

(1) For the General Convention of the Episcopal Church, Detroit, Michigan, July 1988, Short article describing the research projects being conducted in Infectious Disease Service/DMPC at FAMC.

Haburchak DR, Harrison SM, Hannon RN, Miles FW: Human Immunodeficiency Virus Infections and Guild - A Need for Physician Chaplain Liaison. (In Draft).

Letter to the Editor of the Colorado Episcopalian, dated June 1989.

Presentations:

(1) Psycho-social-spiritual Aspects of HIV+Patients: Presented: Ft. Leavenworth, Kansas, September 1987.

(2) AIDS for professionals, The Next Step. 2 presentations: "Guilt, Shame, and Grief" and "A Wellness/wholeness Approach for the HIV+ Patient." New York City, 15 April 1988.

(3) Episcopal Diocese of Colorado Workshop: AIDS, The Church's Response. w/Mr. Hannon and Dr. Harrison. Presented: Denver, Colorado, 6-7 February 1988.

(4) HIV/AIDS Briefing - Psycho-social-spiritual Aspects. Physical Therapy Students. Presented: University of Colorado Medical Center, Denver, CO, April 1988.

(5) HIV/AIDS Briefing/A Psycho-Social-Spiritual Model of Wellness in the HIV+ Patient. Presented: MEDDAC, Ft. Hood, Texas, May 1988.

(6) Workshop on Ministry to the HIV+Soldier/AIDS Ministry. Presented four times; FORSCOM/TRADOC Chaplains' Conference, St. Luis, MO, December 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/105 (3) Status: Terminated

(4) Title: Detection of Unsuspected Disease by the Complete Physical Exam

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: (8) Facility: FAMC  
Homer J. LeMar, Jr., MAJ, MC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators  
Michael J. Weaver, COL, MC

(11) Key Words:  
physical exam  
screening

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine which specific areas of routine screening physical examination of patients at the time of hospital admission detects unsuspected disease, and leads to significant changes in medical management.

(16) Technical Approach: The study will consist of a chart review of in-patient records of patients who were admitted to, and discharged alive from the general medicine wards, after a hospital stay of more than three days. Only charts with a complete admission history and physical examination on the chart will be reviewed. We will begin with 100 charts, and will review more if needed to find sufficient "unexpected findings. One investigator will review the admission history, including the presenting or chief complaint, the history of the present illness,



the past medical history, and the review of systems, without knowledge of the physical examination. All positive findings in the history will be listed, and for each historical finding, we will determine what areas of the physical examination would be pertinent, or in which abnormal findings should be sought and might be expected. These areas of the physical examination will be considered "diagnostic" rather than "screening." The other investigator will review the physical examination, without knowledge of the history, listing all abnormal physical findings, by area. We will then compare the results of the review of the history with the review of the physical examination to determine the yield of the "screening" examination, that is, which physical findings, if any, would not have been expected from the history, or would not have been discovered on examination of only historically relevant or indicated areas. We will then review each chart in detail to determine what tests were done to evaluate the unexpected physical findings, and what changes in management or therapy occurred as a result of these unexpected findings. Based on this, we will determine the utility, or contribution to patient care, of the "screening" physical examination.

(17) Progress: Eighty-three of one hundred charts have been reviewed. Due to computer problems in PAD, several delays in getting charts occurred. Our goal is to review 100 charts.

Publications and Presentations: Presented at Letterman Present Concepts Meeting October 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/106 (3) Status: Ongoing

(4) Title: Use of Nifedipine Gastrointestinal Therapeutic System in the Treatment of Hypertension

(5) Start Date: Sep 1988 (6) Est Compl Date: 1989

(7) Principal Investigator: J. Hasbargen, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology Svc. (10) Associate Investigators V. Bray

(11) Key Words:  
nifedipine  
hypertension

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 3  
d. Total Number of Subjects Enrolled to Date: 10  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To assess the efficacy of the gastrointestinal therapeutic system utilizing nifedipine in the control of hypertension.

(16) Technical Approach: Study with baseline, titration, and efficacy phases study. Blood studies and baseline and after 12 week efficacy period.

(17) Progress: Ten patients enrolled, 3 completed entire study. Six patients did not meet required BF measurements during baseline. One patient withdrew for personal reasons.

Publications and Presentations: Abstract presented at Am. Heart. Assn. Meeting with all collaborative centers.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/108 (3) Status: Terminated

(4) Title: The Effect of Thyroid Hormone Administration in Acute Renal Failure

(5) Start Date: (6) Est Compl Date: 1991

(7) Principal Investigator: J. Lockard, MD (8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology Svc. (10) Associate Investigators M. Dorogy

(11) Key Words:  
acute renal failure  
thyroxine

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Nov/88 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Efficacy of thyroxine in amelioration of acute renal failure.

(16) Technical Approach: Thyroxine vs placebo to patients with ARF. Serum creatinine, urine output followed. T4, TSH will be assayed at WRAMC.

(17) Progress: This is a collaborative study. One patient enrolled and no adverse effects. Principal Investigator transferred hence protocol terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/109 (3) Status: Ongoing

(4) Title: Methotrexate in the Treatment of Steroid Dependent  
Asthmatics

(5) Start Date: (6) Est Compl Date: 1989

(7) Principal Investigator: (8) Facility: FAMC  
Thurman R. Vaughan, MAJ, MC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators

(11) Key Words: David L. Goodman, LTC, MC  
asthma, steroid dependent  
methotrexate

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 1  
d. Total Number of Subjects Enrolled to Date: 11  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effectiveness of weekly  
methotrexate in reducing the steroid requirements of steroid dependent  
asthmatics. The purpose is to demonstrate a statically significant  
reduction in the steroid dose over the placebo control, without involve-  
ment of the other parameters.

(16) Technical Approach: Double blind crossover design with methotrexate  
and placebo following pulmonary function tests, symptom scores with at-  
tempt to taper corticosteroids.

(17) Progress: Eleven patients have entered the study and 10 have  
completed the study. The remaining 1 will complete the study in 6-8  
weeks.

Presentations:

Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid  
dependent asthmatics. Presented: Harold S. Nelson Symposium, FAMC, Feb  
89.

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Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid dependent asthmatics. Presented: Aspen Allergy Conference, Aspen, CO July 1989.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/110A (3) Status: Ongoing

(4) Title: Biological Investigation of Cutaneous Lupus Employing  
Athymic Mice as Skin Heterotransplant Recipients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Ramsey Mellette, COL, MC  
Lela Lee, M.D. UCHSC

(9) Dept/Svc: MED/Dermatology Svc. (10) Associate Investigators

(11) Key Words: Larry Urry, MAJ, MC  
Don Mercill, DAC  
Silvija Coulter, UCHSC  
James Fitzpatrick, LTC, C  
William Weston, MD, UCHSC  
Charles F. Ferris, CPT, MS

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an in vivo model demonstrating  
cutaneous lupus as manifested in humans and to use such model to sequen-  
tially study the biological causes of the diseases.

(16) Technical Approach: See Protocol.

(17) Progress: Due to the limited time devoted to animal research, we  
have decided to submit a manuscript regarding the results of the initial  
protocol to a referee journal in order to obtain comments regarding the  
initial data in hopes of directing follow up studies in the appropriate  
manner.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/111 (3) Status: Ongoing

(4) Title: The Use of Fibrin Monomer and D-Dimer in the Evaluation of Patients with Chest Pain

(5) Start Date: April 1988 (6) Est Compl Date: April 1989

(7) Principal Investigator: Mark E. Dorosy, CPT, MC  
Robert W. Hull, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Internal Med Svc (10) Associate Investigators

Leo W. Jordan, MAJ, MC

(11) Key Words: fibrin monomer  
D-dimer  
unstable coronary artery disease  
Steven H. Atchley, MAJ, MCC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 20  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the diagnostic usefulness of fibrin monomer and D-dimer in patients presenting with chest pain requiring evaluation for unstable coronary disease. To determine the prognostic value of these levels in patients with unstable angina and acute myocardial infarction.

(16) Technical Approach: Patients admitted to the CCU for evaluation of chest pain are divided into two groups - those with unstable coronary d3 (MI, unstable angina), and those determined to have noncardiac chest pain based on initial history and physical, EKG, serial CK determinations and additional workup (TMST, cardiac cath, etc.). Blood is drawn at the time of admission for determination of fibrin monomer and D-dimer levels.

(7) Progress: Initial sample of 20 patients was collected, the D-dimer ELISA was modified to provide extended use with each kit, and the fibrin monomer and D-dimer test assays were run. Fibrin monomer test was not found to be useful and its measurement discontinued.

Publications and Presentations: Information is to be presented in abstract form at the 1988 Army ACP meetings, Cardiology section by Dr. Hull.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/112 (3) Status: Ongoing

(4) Title: Long Term 5-Fluorouracil Infusion for Recurrent Head and Neck Cancer

(5) Start Date: 1988

(6) Est Compl Date:

(7) Principal Investigator:  
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hem/Oncol Svc

(10) Associate Investigators

Frank Ward, MAJ, MC

(11) Key Words:

Denis Lanier, LTC, MC

Patrick W. Cobb, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The study is designed to assess the effectiveness of a continuous infusion of 5-FU on patients with recurrent head and neck cancer. Tumor response, toxicity and survival will be monitored.

(16) Technical Approach: See Protocol.

(7) Progress: No patients entered at FAMC.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/113 (3) Status: Ongoing

(4) Title: Methotrexate versus D-Penicillamine in Rheumatoid Arthritis: A Randomized Comparative Study

(5) Start Date: 1988

(6) Est Compl Date: 1991

(7) Principal Investigator:  
James D. Singleton, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology Svc (10) Associate Investigators  
Sterling G. West, LTC, MC

(11) Key Words:  
methotrexate  
D-penicillamine  
rheumatoid arthritis

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 9  
d. Total Number of Subjects Enrolled to Date: 27  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare clinical efficacy, toxicity and radiographic progression of joint disease in patients receiving methotrexate or D-penicillamine.

(16) Technical Approach: Patients with rheumatoid arthritis will be randomly assigned to receive either methotrexate or D-penicillamine. Clinical assessment will be performed every 3 months and radiographic assessment every year.

(7) Progress: A total of 27 pts have now been in enrolled in study; there have been no withdrawals; 2 patients have been changed from one study drug to the other due to nausea; preliminary results show comparable toxicity and efficacy between the two drugs with MTX patients clearly responding faster than those on D-Pen.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/114 (3) Status: Completed

(4) Title: Crossover Comparison of Maximum Dose Glyburide and Glipizide

(5) Start Date: 1988

(6) Est Compl Date: 1989

(7) Principal Investigator:  
Kenneth J. Simcic, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators  
Michael T. McDermott, LTC, MC

(11) Key Words:  
diabetes (type II)  
oral hypoglycemic agents  
glyburide  
glipizide

Gerald Kidd, COL, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 28  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To examine whether or not significant improvements in fasting serum glucose, hemoglobin A1C1 and blood lipids occur when type II diabetic patients' failing therapy with either glyburide or glipizide are switched to the alternate second generation sulfonylurea agent.

(16) Technical Approach: This trial is a single-center prospective, open crossover study in which type II diabetic patients are switched from a maximum dose of one second-generation sulfonylurea agent (glyburide or glipizide) to the maximum dose of the other agent.

(7) Progress: The study has been completed. 26 patients completed the study; 2 patients were dropped because of intercurrent illnesses that developed. There have been no complications or adverse effects.

Publications and Presentations: Manuscript being prepared for publication.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/115 (3) Status: Ongoing

(4) Title: The Impact of an Ambulatory Care Rotation on Interns  
Psychosocial Attitudes

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Michael J. Weaver, COL, MC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 8  
d. Total Number of Subjects Enrolled to Date: 8  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose to test the hypotheses that this ambulatory care rotation will result in increased awareness of psychosocial problems and the increase in awareness will be correlate with an increase in knowledge of psychosocial content.

(16) Technical Approach: Each intern who does a one month ambulatory care rotation in the internal medicine clinic is given a cognitive knowledge test and a psychosocial attitudes questionnaire at the beginning of the rotation, and again at the end of the rotation.

(17) Progress: We have completed testing the first 8 interns during the training 1988-89. We will continue testing the next 8 interns who are scheduled to have the ambulatory care rotation through June 1990.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/116A (3) Status: Ongoing

(4) Title: Mouse Anti-Chenopod/Amaranth Pollen Monoclonal  
Antibody Production

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Richard W. Weber, COL, MC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators  
Thurman R. Vaughan, MAJ, MC  
(11) Key Words: Lawrence V. Larsen, CPT, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop mouse monoclonal antibodies to chenopod-amaranth pollen antigens. The purpose is to use these antibodies to study the crossreactivity of chenopod-amaranth pollen antigens. The importance of the latter is the eventual improvement of allergen extracts for diagnostic and therapeutic utilizations.

(16) Technical Approach: Stage I: Characterization of allergen extracts by PAGE and Western Blot. Stage II: Monoclonal antibody production and characterization by injecting mice with allergen extract, screen for antibody with ELISA, and develop hybridomas.

(17) Progress: Have obtained monoclonal antibody against two antigenic determinants to the weed russian thistle; have shown by Western Blot that these two determinants occur in several molecular weight protein species; have shown that limited crossreactivity exists for the monoclonal antibodies between russian thistle and kochia; have polyclonal sera for redroot pigweed, kochia.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/117 (3) Status: Ongoing

(4) Title: A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvants to Opiate Analgesics in the Management of Pain in Cancer Patients

(5) Start Date: 1988

(6) Est Compl Date:

(7) Principal Investigator:  
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hemo/Oncol Svc

(10) Associate Investigators  
Rose A. Gates, MAJ, ANC

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May 89 b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 3  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NONE

(15) Study Objective: a. To compare the relative effectiveness of amitriptyline and trazodone as adjuvants to opiate analgesics for the management of pain of malignant diseases; b. Quantify the "opiate sparing" effect of these two agents when used in conjunction with morphine sulfate; c. Evaluate the cost-efficiency/effectiveness of trazodone and amitriptyline, as adjuvants to opiate analgesics in the treatment of pain associated with malignant disease.

(16) Technical Approach: See protocol.

(7) Progress: Three subjects at Fitzsimons. One of our patients receiving an antidepressant noted a difference in pain control when the study medication was withdrawn.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/118 (3) Status: Ongoing

(4) Title: CAP Study 12-21-87 - Use of Nifedipine (Gastrointestinal Therapeutic System) in the Treatment of Angina Pectoris

(5) Start Date: 1988 (6) Est Compl Date: 1989

(7) Principal Investigator: Richard C. Davis, Jr., COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Cardiology Svc (10) Associate Investigators  
John M. VanDeren, III, CPT, MC

(11) Key Words:  
nifedipine GITS  
angina pectoris  
silent ischemia

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 5/89 b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 8  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To establish the efficacy of Nifedipine GITS as monotherapy or combined therapy with beta blockers in angina pectoris. Secondly, to try to clarify some of the issues regarding mechanism of action of a new delivery system, Nifedipine GITS compared to other anti-anginal therapies.

(16) Technical Approach: Qualified patients will be placed on Nifedipine GITS placebo in a single blind fashion after all other antianginal therapy except beta blockers are discontinued. They will then undergo Holter monitoring. Those with objective evidence of ischemia will be placed on Nifedipine GITS and dose titrated over 7-12 weeks to maximum efficacy with Holter monitoring performed at the completion of the efficacy phase. A single blind placebo control period will then be repeated with Holter monitoring at the completion.

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(7) Progress: To date, eight patients have been enrolled in the study, five patients have been dropped after the first placebo control period due to lack of ST changes on Holter monitoring. One patient has been dropped from the study due to significant resting ST segment depression. Two patients have completed the study. These two individuals responded well to the study drug with marked improvement in frequency of angina. They are currently on chronic long term drug therapy and doing well. Holter monitoring did not reveal significant change in the frequency of silent ischemia in these two individuals. No problems encountered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/119 (3) Status: Completed

(4) Title: The Effects of Verapamil and Diltiazem on Gastric Emptying

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Robert T. Yavorski, CPT, MC  
Scott E. Hallgren, MAJ, MC

(9) Dept/Svc: Int. Med. Svc. (10) Associate Investigators:  
Peter W. Blue, COL, MC

(11) Key Words:  
verapamil  
cardizem  
gastric emptying

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 8\88 b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 10  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine gastric emptying rates in subjects at baseline and after ingesting either verapamil or cardizem.

(16) Technical Approach: Gastric emptying performed by ingesting a beef stew meal impregnated with techresin sulfur without eggs. Scanning performed in nuclear medicine department using both ant. and posterior scanning techniques.

(17) Progress: Results revealed no significant difference in gastric emptying rates between baseline and after ingestion of either verapamil or cardizem in all 10 subjects.

Publications and Presentations: Abstract submitted to the gastroenterology subsection of the Army ACP meeting to be held in October 1989.



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/120 (3) Status: Ongoing

(4) Title: Ventilatory Effects of Transtracheal Oxygenation

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Michael Perry, COL, MC  
Peter Blue, COL, MC

(9) Dept/Svc: MED/Pulmonary Dis. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 10  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate the ventilatory effects of transtracheal oxygen therapy.

(16) Technical Approach: A group of 10 COPD patients will have their resp. parameters measured while receiving supplemental oxygen through a nasal cannula and then again while receiving transtracheal oxygen at a flow rate equivalent to that of the nasal cannula. The 2nd part of the study will examine the effects of transtracheal oxygen on radioactive xenon wash.

(17) Progress: Pending 2 nuclear medicines to complete. Ten patients enrolled.

Publications and Presentations: HMLAC, Oct 88; Army ACP meeting; An. Thoracic Soc. May 89; Abstract: Review of Am. Respiratory, Apr 89.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/121 (3) Status: Ongoing

(4) Title: Bone Densitometry in Thyroid Extract Treated Patients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: William J. Georgitis, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether thyroid extract has greater adverse effects on bone density and calcium metabolism than synthetic l-thyroxine. The second is to assess the reversibility of any documented effect.

(16) Technical Approach: The effects of thyroid extract treatment on bone densitometry will be investigated. Subjects taking thyroid extract treatment matched with a thyroxine controlled group will have assessments of thyroid replacement therapy status, mineral metabolism and bone density. Thyroid extract subjects found to be subclinically hyperthyroid may enter a longitudinal assessment of bone density after crossing over to euthyroid thyroxine replacement.

(17) Progress: From eighty-five refill prescriptions for thyroid extract, seventy-one patients were sent letters. Twenty-eight potential subjects were counseled about the study and twenty have been studied.

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT    Protocol #: 88/121

Sixteen of the twenty show evidence of excessive replacement with thyroid extract. Eight of these subjects have crossed over to thyroxine and six have achieved euthyroid profiles. Bone densities were not found to be significantly different from age adjusted normals except at the femoral trochanter where the mean z score for the patients was 0.6 (P less than 0.04).

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/122 (3) Status: Ongoing

(4) Title: LCSG 881 - A Randomized Phase II Study of Preoperative  
Therapy for Patients with Technically Unresectable  
Non Small Cell Lung Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Thomas Cosgriff, COL, MC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the LCSG group protocol.

(16) Technical Approach: See Protocol

(17) Progress:

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/123 (3) Status: Terminated

(4) Title: Non-Invasive Estimation of Prosthetic Aortic Valve  
Area Using Doppler Ultrasound

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
William T. Highfill, MAJ, MC

(9) Dept/Svc: MED/Cardiology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 7  
d. Total Number of Subjects Enrolled to Date: 7  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if Doppler ultrasound, using the equation of continuity, can accurately estimate the effective area of prosthetic valves in the aortic area.

(16) Technical Approach: This study will involve an echocardiographic evaluation (non-invasive) of patients who have recently undergone aortic valve replacement, or normals for valve performance.

(17) Progress: Seven patients were enrolled prior to termination of study; due to technical problems in measuring the LVOT in patients with prosthetic aortic valves, a key measurement could not be made in the majority of patients, invalidating the use of the continuity equation in this condition. The study was discontinued at all centers (WRAMC, BAMC, FAMC) for that reason. (Note: This examination, however, is still performed in all patients following valve replacement for clinical reasons).

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/124 (3) Status: Ongoing

(4) Title: Corticosteroids in the Treatment of Stable Chronic  
Obstructive Pulmonary Disease

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Thurman R. Vaughan, MAJ, MC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:  
David L. Goodman, LTC, MC

(11) Key Words:  
COPD  
obstructive lung disease  
corticosteroids

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 4  
d. Total Number of Subjects Enrolled to Date: 4  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine if subjects with severe obstruction  
lung disease would benefit from extended therapy with corticosteroids.

(16) Technical Approach: Approximately 10 subjects who have COPD that  
is not responsive to maximal beta-agonist therapy will be enrolled  
(elevated FEC, <10%) they will then be randomized to receive either 32mg  
methylprednisolone per day or placebo for 4 weeks followed by a washout  
period of 4 weeks and finally crossover to receive the alternate drug.  
Spirometry and body plethysmography will be performed prior to beginning  
the study and at 2 week intervals throughout the study period.

(18) Progress: Four subjects enrolled; 2 in the final 4-week period.  
Patient recruitment is somewhat difficult in the most "irreversible"  
COPD subjects have demonstrated a >10% response to Q2 therapy.

Publications and Presentations: None

(1) Date: 30 Sep 89 (2) Protocol #: 88/125 (3) Status: Completed

(4) Title: Investigation of the Effects of Synthetic Corticotropin Releasing Factor (CRF) on Pituitary Adrenal Function in Man

(5) Start Date: Sep 88 (6) Est Compl Date:

(7) Principal Investigator: Dirk R. Davis, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators: Michael T. McDermott, LTC, MC

(11) Key Words:  
corticotropin releasing factor (CRF)  
corticotropin (ACTH)  
cortisol

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 5  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the interindividual and intraindividual variation in the ACTH and cortisol responses to acute CRF administration.

(16) Technical Approach: Five subjects each have 5 separate CRF stimulation tests, all at least one week since the last test. Each test is performed at 1830 hrs and is identical in all respects to allow CRF tests. A 5x5 matrix design is to be utilized for statistical analysis.

(17) Progress: All 5 subjects have completed the study (25 total tests). Cortisol and ACTH measurements show that intraindividual variation is similar to interindividual variation but the full statistical analysis is pending.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/100 (3) Status: Ongoing

(4) Title: The Application of Orem's Self-Care Model in Type II Diabetes: An Outcome Study of Diabetic Self-Care Classes and Self-Care Contracting Comparing Self-Care Knowledge, Health Care Beliefs, Weight Loss and Metabolic Control

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Ann Marie Bianchi, MAJ, An (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators: Nancy Pfander, MAJ, AN

(11) Key Words:  
noninsulin dependent diabetes  
Orem's self-care model  
locus of control  
contract vs noncontract

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 24  
d. Total Number of Subjects Enrolled to Date: 24  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To examine whether Type II (NIDDM) clients who attend diabetic self-care classes and also contract for specific self-care activities will significantly gain in self-care knowledge and activities as measure by knowledge questionnaire, Locus of control tool, wt. control, and metabolic control (FBS, HgbA1c, chol, TG), relative to those who do not contract for self-care behaviors.

(16) Technical Approach: Subjects were randomly selected from type II diabetic clients referred for diabetic education. They were given a pretest questionnaire. The locus of control tool was also given to elicit information about subjects' health beliefs. Metabolic data (FBS, HgbA1c, chol, TG) was also obtained. The clients were then randomly assigned to the contract or noncontract group. The above data will be collected again at 3 mo., 6 mo., and at 12 months.

(17) Progress: Twelve clients have completed only the first 3 mo., 12 have completed the first 6 months of the study. 6 others were initially recruited but do not remain because they moved, never completed initial labs, or could not be reached for the 3 mo. followup.



CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol #: 89/100

Publications and Presentations: The 3 month data is being used by MAJ Bianchi to complete a thesis for graduate school.

Publications and Presentations:

(1) Date: 30 Sep 89 (2) Protocol #: 89/101 (3) Status: Completed

(4) Title: Transtracheal Oxygen and the Perception of Dyspnea:  
Parts I and II

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Marin H. Kollef, CPT, MC

(9) Dept/Svc: MED/Pul. Dis. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Part I: To demonstrate the effects of transtracheal oxygen therapy on the dyspneic, hypoxemic patient with COPD. Part II: To compare nasal canula oxygen therapy to transtracheal oxygen therapy in terms of their effects on patient dyspnea.

(16) Technical Approach: Part I: Blood samples will be obtained from a radial artery catheter after the subject breathes air or oxygen at two different flow rates. Lidocaine will be applied through the transtracheal catheter and the same samples repeated after again breathing the air or oxygen at different flow rates. Part II: A nasal canula will be applied to the subject. In a random manner oxygen will be administered via the transtracheal catheter or the nasal canula, and the sensation of breathlessness will be assessed with the visual analog scale. The same schema outlined above will be repeated after the subject has 5 cc of 1% lidocaine instilled in the trachea via the transtracheal oxygen catheter and the nares anesthetized with 10% lidocaine jelly.

(17) Progress: I have decided to terminate the part B due to lack of clinical benefit of doing the study and recent report on this type of data already. Part A has been published as below.

Presentations: None

Publications: Submitted to Archives of Internal Medicine.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 89/102 (3) Status: Ongoing

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(4) Title: Factors Determining Peak Bone Mass and Subsequent Bone Loss

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(5) Start Date: (6) Est Compl Date:

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(7) Principal Investigator: (8) Facility: FAMC  
Michael T. McDermott, LTC, MC  
Gerald S. Kidd, COL, MC  
Peter W. Blue, COL, MC  
Harry N. Tyler, Jr., DAC

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(9) Dept/Svc: MED/Endocrinology (10) Associate Investigators:

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(11) Key Words:  
bone density  
peak bone mass

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

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(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

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(15) Study Objective: To determine factors associated with the development of peak bone mass and subsequent bone loss.

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(16) Technical Approach: Bone density of the radius (single photon absorptiometry) and of the hip and spine (dual photon absorptiometry) will be done in a large group of male and female volunteers, who will also, on another protocol, be having total body fat and lean mass measured by dual photo absorptiometry. Questionnaire concerning present and past calcium intake, exercise and other habits will also be administered.

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(17) Progress: No progress yet since the accompanying protocol involving total body fat and lean mass measurements has yet to begin.

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Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/103 (3) Status: Ongoing

(4) Title: Transient Hypoxia During Sedated Endoscopic Procedures

(5) Start Date: Dec 88 (6) Est Compl Date: Jun 89

(7) Principal Investigator: Steven P. Lawrence, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastroent

(10) Associate Investigators:

(11) Key Words:  
endoscopy  
hypoxia

Stephen Freeman, LTC, MC  
Scott Hallgren, MAJ, MC  
Jeffrey Dunkelberg, MAJ, MC  
John Van Deren, CPT, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of transient hypoxia during sedated endoscopy and correlate this with changes in blood pressure, cardiac rhythm, over all clinical status of the patient and type and/or stage of endoscopy.

(16) Technical Approach: Room air arterial oxygen saturation, blood pressure and heart rate will be recorded prior to, during and after intravenous sedation and endoscopy.

(17) Progress: Currently no work is being done on this project until minor problems in analysis of data from monitoring devices is resolved.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/104 (3) Status: Ongoing

(4) Title: Efficacy of Corticosteroids in the Acute Treatment of  
Asthma: Is Duration of Symptoms Important?

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 91

(7) Principal Investigator: (8) Facility: FAMC  
Thurman R. Vaughan, MAJ, MC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators:  
David L. Goodman, LTC, MC

(11) Key Words:  
asthma  
corticosteroids  
emergency management

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if the beneficial effect of  
corticosteroids seen in the treatment of status asthmatics is dependent  
on the duration of asthmatic symptoms.

(16) Technical Approach: 120 subjects presenting to the E.R. or allergy  
clinic with acute episode of asthma will be studied. Subjects will  
receive either 125mg methylpredisolone or placebo within 30 minutes of  
arriving for tx. They will be divided into 2 sps - these with IRS of  
<24 hours duration and those with sxs for more than 24<sup>0</sup>. Spirometry and  
admission rate will be analyzed.

(17) Progress: Pharmacy and ER staff have been consulted and have  
agreed to participate in the study. We are currently awaiting an  
associate investigator (Dr. Goodman) so that the protocol can procede.  
Anticipate beginning this study in September.

Publications and Presentations: None

(1) Date: 30 Sep 89 (2) Protocol #: 89/105 (3) Status: Ongoing

(4) Title: Role of Blood Pressure Control in Progression of  
Diabetic Nephropathy and Other Microangiopathies

(5) Start Date: Dec 88 (6) Est Compl Date: Dec 93

(7) Principal Investigator: Robert J. Sjoberg, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:  
Gerald Kidd, COL, MC  
(11) Key Words: nephropathy  
diabetes Joseph White, MAJ, MS

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: a) Define a level of blood pressure control in a prospective, randomized, non-blinded fashion needed to prevent or delay the progression of diabetic nephropathy and other microvascular complications of diabetes; b) determine if there is a specific advantage to either a CEI or a Ca++ channel blocker as a mode of treatment for hypertension in regard to the onset or progression of diabetic nephropathy.

(16) Technical Approach:

(17) Progress: None. Currently awaiting FDA approval of investigational new drug, Nitrendipine. Additional coordination with other participating institutions is required before initiating this study.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/106 (3) Status: Ongoing

(4) Title: Immunologic Criteria for the Cessation of Immunotherapy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: James S. Brown, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc. (10) Associate Investigators:  
Richard W. Weber, COL, MC  
(11) Key Words: Robert Stewart, MAJ, MS

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 21  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the presence of a marker for long term efficacy of immunotherapy.

(16) Technical Approach: A. Identifiable change in sub-populations of lymphocytes with immunotherapy; B. Identification of anti-idiotypic antibodies to allergens; C. Demonstration of effect of immunotherapy on late-phase skin tests.

(17) Progress: Delays have occurred with the development of various assays. The three areas of investigation appear to be nearly ready. We have shown an interesting non-specific adhesion of allergen to b-cells.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/107 (3) Status: Ongoing

(4) Title: A Multicentric Observer-Blind, Randomized Study  
of the Safety, Efficacy and Tolerance of Cefpirome  
(HR-810) Versus Ceftazidime in the Treatment of  
Pneumonia

(5) Start Date: 1989

(6) Est Compl Date: 1991

(7) Principal Investigator:  
Richard E. Winn, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pul.Dis.

(10) Associate Investigators:  
Shannon Harrison, LTC, MC  
William E. Caras, MAJ, MC  
Ray C. Johnson, MAJ, MC  
Marin H. Kollef, CPT, MC

(11) Key Words:  
pneumonia  
Cefpirome Ceftazidime

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: As per title.

(16) Technical Approach: Refer to Hoechst-Roussel Pharmaceuticals,  
Inc., investigational drug study protocol 203.

(17) Progress: No patients enrolled to date.

Publications and Presentations: None.



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/108 (3) Status: Ongoing

(4) Title: Efficacy of Pentoxifylline in Treating Diabetic  
Impotence

(5) Start Date: 1989 (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC  
J o h n A . M e r e n i c h , C P T , M C

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:  
Clyde Roy, MAJ, MC  
(11) Key Words: Nancy Pfander, MAJ, MC  
diabetes William Georgitis, LTC, MC  
impotence Gerald S. Kidd, COL, MC  
Pentoxifylline Ernie Lin, LTC, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if pentoxifylline is more effective  
than placebo in improving sexual function in non-insulin dependent  
diabetic men.

(16) Technical Approach: A single center, double-blind, placebo  
controlled study to examine the efficacy of pentoxifylline in improving  
sexual function in impotent NIDDM men. Diabetic men with impotence who  
meet the protocol entrance criteria will be randomly assigned placebo  
or pentoxifylline for 12 weeks. After completion of the treatment  
course subjects will be reevaluated, and groups will be compared to  
determine beneficial effects.

(17) Progress: No progress has been made on this study. Necessary  
equipment is still on order.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/109 (3) Status: Ongoing

(4) Title: The Effect of Percutaneous Endoscopic Gastrostomy  
Tube Placement on Gastric Emptying

(5) Start Date: Jan 89

(6) Est Compl Date: Dec 89

(7) Principal Investigator:  
James E. Cremins, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med.

(10) Associate Investigators:  
Jeffery Dunkelberg, MAJ, MC  
Stephen Freeman, LTC, MC  
Scott E. Hallgren, MAJ, MC  
Peter Blue, LTC, MC

(11) Key Words:  
gastric emptying  
gastrostomy tube

(12) Accumulative MEDCASE:\*  
Refer to Unit Summary Sheet of this Report

(13) Est Accum OMA Cost:\*

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To define the effect of PEG placement on gastric  
emptying.

(16) Technical Approach: Baseline gastric emptying studies will define  
subjects' status prior to PEG placement. Repeat gastric emptying  
studies at definite intervals post procedure will allow detection of any  
changes in gastric emptying. This will impact possibly on defining a  
standard approach to feeding these patients.

(17) Progress: To date only two patients have been enrolled who meet  
the inclusion criteria. However, both subjects expressed significant  
improvement in life by study participation, and one subject has actually  
gained weight while on protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/110 (3) Status: Ongoing

(4) Title: Cyclic Oxygen Therapy at Rest and During Exercise

(5) Start Date: Jan 89

(6) Est Compl Date: Jun 89

(7) Principal Investigator:  
Ray C. Johnson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pul. Dis.

(10) Associate Investigators:  
Michael E. Perry, COL, MC  
Peter Blue, COL, MC

(11) Key Words:  
cyclic oxygen therapy

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to  
Date: 10 \_\_\_\_\_ e. Note any adverse drug reactions  
reported to the FDA or sponsor for studies conducted under an  
FDA-awarded IND. May be continued on a separate sheet, and designated  
as "(14)e"

(15) Study Objective: To determine if cyclic oxygenation can be used  
as an oxygen conservation measure. To determine physiologic correlates  
of efficacy.

(16) Technical Approach: A "baseline" continuous flow rate will be  
determined for each subject. The timing sequence and cycling flow will  
identify the corrected cycle flow for each subject at rest. The studies  
will be repeated while the subjects exercise to ascertain exercise  
baseline flows as a benchmark for comparison, to determine optimum  
timing sequences independent of resting conditions and to determine the  
effect of higher cycling flows.

(17) Progress: Preliminary findings indicate some people have good  
response to this therapy (two out of ten). The other subjects did not  
experience benefit. No subjects experienced adverse reactions.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/111 (3) Status: Ongoing

(4) Title: Multicenter Clinical Evaluation of Penicillin  
Skin Testing Materials

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
James S. Brown, LTC, MC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:

(11) Key Words: Robert Ledoux, DAC  
penicillin  
minor determinants

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 31  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the optimal test reagent in assessment for anaphylactic grade sensitivity to minor determinants of penicillin.

(16) Technial Approach: Prick and intradermal skin testing.

(17) Progress: 27 subjects have been enrolled at FAMC showing 4 reactive to MDM-A, 3 reactive to MDM-B, 9 reactive to the "Sullivan" formula, two reactions also occurred to Pen G, and three to Pre-pen. Four subjects have been reported from Tripler AMC, only one small pos was shown to Pre-pen. San Diego Naval Hospital approval is near, and protocols have been submitted at Madigan, Bethesda Naval Center, and Letterman. Wilford Hall has shown interest but no protocol has been submitted as yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/112 (3) Status: Ongoing

(4) Title: The Use of Megestrol Acetate to Treat Cachexia in  
Patients with Chronic Obstructive Pulmonary Disease  
and the Possible Improvement of Pulmonary Function

(5) Start Date: Apr 89 (6) Est Compl Date: Apr 90

(7) Principal Investigator: James I. Meyer, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary (10) Associate Investigators:  
Marin Kollef, CPT, MC  
(11) Key Words: Michael E. Perry, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 2  
d. Total Number of Subjects Enrolled to Date: 2  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e" None

(15) Study Objective: To se if patients with COPD improve pulmonary  
function with wt gain 2<sup>0</sup> to using megestrol.

(16) Technical Approach: Clinial Trial.

(17) Progress: Two patients enrolled to date, no results yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/113 (3) Status: Ongoing

(4) Title: LCSG NC 3 Natural History Registry for Patients with  
Stage II Non-Small Cell Lung Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hem/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the LCSG group protocol.

(16) Technical Approach: See Protocol.

(17) Progress: Continuing to accrue.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/114 (3) Status: Ongoing

(4) Title: Response of Arthritis and Microscopic Colitis to Sulfasalazine in Rheumatoid Arthritis Patients

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Raymond J. Enzenauer, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Rheumatology (10) Associate Investigators: Sterling G. West, MD  
(11) Key Words: James Singleton, MD  
Stephen Freeman, MD  
Kenneth Sherman, MD, Ph.D.

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: 5 Sept 1989 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: 3 ctrl biopsies  
d. Total Number of Subjects Enrolled to Date: 3 control patients  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the effect of sulfasalazine on both microscopic colitis and arthritis in RA.

(16) Technical Approach: See Protocol.

(17) Progress: 3 control patients admitted per GI service. No NSAID only patients. No new RA patients begun on sulfasalazine during first 12 months since protocol approval.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/115 (3) Status: Ongoing

(4) Title: The Effect of Congestive Heart Failure (CHF) on the Erythrocyte Sedimentation Rate (ESR)

(5) Start Date: Aug 89 (6) Est Compl Date: Aug 90

(7) Principal Investigator: Mitchell Kruger, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Cardiology Svc (10) Associate Investigators: Raymond Enzenauer, MAJ, MC

(11) Key Words:  
congestive heart failure  
erythrocyte sedimentation rate

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish the effect of acute uncomplicated CHF on the ESR and attempt to analyze specific variables affecting the ESR in the setting of CHF.

(16) Technical Approach: Fifty patients evaluated will be admitted for routine elective cardiac catheterization while fifty patients evaluated will be admitted for treatment of congestive heart failure. This study will analyze certain blood chemistries that are not routinely drawn for examination in patients with CHF or for routine cardiac catheterization.

(17) Progress: None. This is newly approved study.

Publications and Presentations: None.



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/116 (3) Status: Ongoing

(4) Title: Atrial Natriuretic Peptide (ANP) Levels in Patients  
With VVI Pacing With and Without Ventriculoatrial (VA)  
Conduction Versus Dual Chamber Pacing

(5) Start Date: Aug 89 (6) Est Compl Date: Oct 89

(7) Principal Investigator: John Madonna, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Internal Medicine (10) Associate Investigators:  
John Van Deren, MAJ, MC

(11) Key Words:  
atrial natriuretic peptide  
pacemaker syndrome

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To obtain data which could possibly add  
information about the pathophysiology of Pacemaker Syndrome.

(16) Technical Approach: To take patients who have a dual chamber  
pacemaker and measure serum ANP levels while they are in dual chamber  
pacing mode, and compare these serum ANP levels with levels obtained  
while these patients are in the VVI pacing mode. We will also document  
VA conduction while in the VVI mode and relate this phenomenon to serum  
ANP levels.

(17) Progress: Patients are being enrolled and data collected.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/117 (3) Status: Ongoing

(4) Title: Evaluation of Thermography in the Delineation of Late Phase Skin Tests

(5) Start Date: Sep 89 (6) Est Compl Date: Mar 90

(7) Principal Investigator: James Brown, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Allergy Svc (10) Associate Investigators:  
Edward Green, COL, MC  
Richard Sherman, MAJ, MS  
Richard Weber, COL, MC

(11) Key Words:  
skin tests  
thermography

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The accurate measurement of the area of involvement in the late phase reaction would enhance this parameter as a tool in studying the immunologic reaction of sensitizing substances.

(16) Technical Approach: Skin test materials will be applied to six allergic and six non-allergic volunteers. The sites will be photographed using the thermographic camera from the time of testing until the maximal immediate reaction has been reached (usually 15-20 minutes), and then photographed hourly for six hours. All studies will be recorded on a VCR. Visual estimations of reaction size will be made by circumscribing the area of involvement with a ballpoint pen and transferring the image to paper using transparent tape.

(17) Progress: Subjects are currently being enrolled in this recently approved study.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/118 (3) Status: Ongoing

(4) Title: Bronchoalveolar Lavage in Intubated Patients with the Adult Respiratory Syndrome for the Evaluation of Fat Emulsion Induced Changes in Alveolar Characteristics

(5) Start Date: Aug 89 (6) Est Compl Date: Jun 90

(7) Principal Investigator: Martin Kollef, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MICU

(10) Associate Investigators:  
Vishnu Reddy, LTC, MC  
James Meyers, CPT, MC

(11) Key Words:  
intravenous fat emulsion therapy  
pulmonary abnormalities

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To examine the ability of bronchoalveolar lavage (BAL) to detect changes in the chemical and histologic properties of the BAL fluid after the administration of intravenous fat emulsion therapy.

(16) Technical Approach: The triglyceride levels in the lavage fluid will be analyzed and compared to one another for ten patients before and after administration of the intralipid. The Oil Red O stains of the lavage fluid will be compared to one another and analyzed for staining within cells and for free floating fat in the fluid itself. Cell counts will be made in the lavage fluid in a standard manner.

(17) Progress: No progress to date on this recently approved study.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/119 (3) Status: Ongoing

(4) Title: Development of a Cardiopulmonary Resuscitation (CPR)  
Information Sheet and Assessment of Patient and Staff  
Response

(5) Start Date: Oct 89 (6) Est Compl Date: Apr 90

(7) Principal Investigator: Rose Gates, MAJ, An (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:  
Michael Weaver, COL, MC  
Robert Gates, MAJ, MC

(11) Key Words:  
cardiopulmonary resuscitation  
do-not-resuscitate order

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: a) To assess the acceptability of an information  
sheet on CPT to both patients and professional staff; b) To determine  
the attitude of patients and professional staff regarding discussion of  
CPR and CPR options.

(16) Technical Approach: A CPR information sheet and questionnaire  
will distributed as per objective. Discussions will be held at the time  
of collection of the questionnaires.

(17) Progress: None. This is a newly approved study.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/120A (3) Status: Ongoing

(4) Title: Mediastinal Tamponade Due to Closed Thoracostomy  
in a Goat

(5) Start Date: Sep 1989 (6) Est Compl Date: Jan 90

(7) Principal Investigator: Marin H. Kollef, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Dis. Svc. (10) Associate Investigators:  
James Meyer, CPT, MC  
(11) Key Words: tamponade  
thoracostomy  
Douglas Dothager, CPT, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To document objectively in an animal model whether a closed thoracostomy tube can cause impairment in cardiac output and thus hypotension by tamponading the inferior vena cava or right ventricle.

(16) Technical Approach: The design of the study is a prospective animal model which will evaluate the above stated hypothesis.

(17) Progress: This recently approved study has not been initiated.

Publications and Presentations:

DEPARTMENT OF SURGERY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 78/20X-001 (3) Status: Ongoing

(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbit

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: James C. Johns, Jr.  
MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedic (10) Associate Investigators

(11) Key Words:  
microvascular education  
and training

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To increase microsurgical technique for orthopedic staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: Continued training/education for resident/interns and students. Continued maintenance of staff skills. Microvascular techniques used for vein grafts, arterial and venous anastomoses, nerve repairs, and grafts.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 78/20X-002 (3) Status: Ongoing

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(4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and the Rat

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(5) Start Date: (6) Est Compl Date: Indefinite

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(7) Principal Investigator: (8) Facility: FAMC  
Kenneth F. Casey, MAJ, MC

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(9) Dept/Svc: SUR/Neurosurgery (10) Associate Investigators

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(11) Key Words:  
microvascular education  
and training

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

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(15) Study Objective: To increase microsurgical technique for staff and residents.

(16) Technical Approach: Perform all microvascular studies/techniques prior to human surgery.

(17) Progress: The aforementioned protocol has been utilized only on two occasions in the last year. This has resulted from difficulty with our ongoing resident training due to manpower shortages. On both occasions of use, however, the personnel involved were able to satisfactorily complete the microsurgical anastomosis, as well as benefit from the exposure.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date 30 Sep 89 (2) Protocol #: 78/20X-003 (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel  
and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
William H. Harpster, COL, MC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Four plastic surgeons have received microvascular  
training using this protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

5) Start Date: 1978

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Floyd M. Cornell, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words

COL John Pope, Jr.  
MAJ Ricardo J. Ramirez  
CPT Thomas A. Gardner  
CPT Eric A. Sieck  
CPT Miles W. Whitaker  
MAJ Jonathan G. Stock  
CPT William T. Walton

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 450  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

3M, ALCON, IOLAB (PRECISION-COSMET), COBURN, CILCO, IOPEX, COPELAND, PHARMACIA INTERMEDICS, SURGIDEV

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: pachymetry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: Results have been excellent with over 1,000 subjects enrolled. No adverse reactions encountered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 78/201 (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Luis Colon, MAJ, MC

(8) Facility: FAMC  
General Leonard Wood Army  
Community Hospital

(9) Dept/Svc: Ophthalmology

(10) Associate Investigators:

(11) Key Words:  
intraocular lens

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results

c. Number of Subjects Enrolled During Reporting Period: 46

d. Total Number of Subjects Enrolled to Date: 46

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient. (See original protocol).

(16) Technical Approach: Extracapsular cataract extraction with posterior chamber IOL.

(17) Progress: Since Sept 1988, 29 posterior and 2 anterior chamber lenses (IOLAB, Corburn, or 3M) have been implanted in aphakic subjects. Subjects have improved eyesight with no adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 78/201.A (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Monte Dirks, MAJ, MC

(8) Facility: FAMC  
Munson ACH  
Ft. Leavenworth, KS  
66027

(9) Dept/Svc: Ophthalmology

(10) Associate Investigators:

(11) Key Words:  
cataract extraction  
intra ocular lens implantg

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 50  
d. Total Number of Subjects Enrolled to Date: 80  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Participation in IOL implantation to meet FDA requirements for safety and efficacy and to improve eyesight in patients having cataracts.

(16) Technical Approach: See Protocol

(17) Progress: Subjects are experiencing improved eyesight with decreased incidence of posterior capsular opacification with bioconvex Coburn lenses. 80 lens have been implanted to date without complications.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol WU#: 78/201.C (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Ricardo J. Ramirez, MC

(8) Facility: FAMC  
Irwin Army Community Hospital  
Ft. Riley, Kansas 66442

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:  
intraocular lens

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 326  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and compare those results with those who undergo cataract surgery without an implant. To determine the occurrence and time of postoperative ocular complications and adverse reactions for intraocular lens implant; to identify subgroups within the implant group that are risk of a particular complication.

(16) Technical Approach: After completing his residency, didactic courses, laboratory practice and assistance with an experienced surgeon, a surgeon who can perform a successful cataract surgery is then allowed to perform intraocular lens surgery. Postoperative examination includes: refraction, pachymetry, keratometry and a complete anterior and posterior segment examination. Contraindications to surgery with intraocular implants include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, any history of anterior or posterior uveitis. History of glaucoma would preclude the use of an anterior chamber implant.

CONTINUATION SHEET, FY 89, ANNUAL PROGRESS REPORT Protocol # 78/201.C

(17) Progress: No complications related to implants thus far.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 78/201.D (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Jeffrey L. Bezier, MAJ, MC

(8) Facility: FAMC  
Reynolds Army Hospital  
Ophthalmology, Box 21  
4700 Hartell Blvd.  
Ft. Sill, OK 73503-6300

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:  
intraocular lens

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 75  
d. Total Number of Subjects Enrolled to Date: 160  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine postoperative visual acuity of patients receiving intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens.

(16) Technical Approach: Post-operative examinations include: Visual acuity testing and keratometry. Contraindications to surgery include: Proliferative diabetic retinopathy, rubeosis irides. Implanting CILCO lenses now, but also authorized to implant Precision Cosmet, 3M, Alcon, and IOLAB.

(17) Progress: Cataract surgery with the intraocular lens implantation has been satisfactory with no unusual post operative complications to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 78/201.E (3) Status: Ongoing

(4) Title: Clinical Study of Intraocular Lens

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Charles E. Aronson, COL MC

(8) Facility: FAMC  
Evans Army Community Hospital  
Ophthalmology, Ft. Carson, CO

(9) Dept/Svc: SUR/Ophthalmology

(10) Associate Investigators

(11) Key Words:  
intraocular lens

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 88  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Participation in IOL implantation.

(16) Technical Approach: See protocol.

(17) Progress: In the last Fiscal Year the Ophthalmology Service has implanted exclusively either the Coburn #72 UV Posterior Chamber or the Coburn #121 UV lens. We have implanted 85 of the 72 UV lens and 3 of the 121 UV lens. The 72 UV lens is our primary lens of choice in patients undergoing extracapsular cataract extractions and we find it to be an excellent lens with good centering ability over a prolonged period. We have not had to reposition or remove any lens because of subluxation or dislocation. There is no evidence of chronic uveitis or late onset hyphema or glaucoma with these lenses. The 121 UV lens (Anterior Chamber) is used as the lens to be placed in patients undergoing secondary lens implantation following a previous cataract extraction or in those patients with vitreous loss due to posterior capsular rupture at the time of the initial extracapsular cataract extract. We have had two complications using this lens, both in the same patient. This is the onset of cystoid macular edema in both eyes of one patient following secondary anterior chamber IOL implants.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 84/20X-001 (3) Status: Ongoing

(4) Title: Microvascular Arterial and Venous Anastomosis in  
Laboratory Rats

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Michael J. Raife  
COLC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology

(10) Associate Investigators  
Thomas A. Jones, MAJ, MC  
Craig Donatucci, MAJ, MC  
Ronald Sutherland, CPT, MC  
James B. Thrasker, CPT, MC

(11) Key Words:  
microsurgery

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To develop and maintain microvascular skills.

(16) Technical Approach: Microsurgical exercises of increasing  
complexity will be performed under anesthesia.

(17) Progress: The protocol has been valuable in teaching microsurgical  
techniques.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol WU#: 86/200 (3) Status: Ongoing

(4) Title: Treatment of Urinary Tract Trauma in the Porcine Animal Model

(5) Start Date: 1986

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Michael J. Raife, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc

(10) Associate Investigators

(11) Key Words:  
renal trauma  
renovascular surgery  
bladder augmentation and  
substitution

James B. Thrasher, CPT, MC  
Thomas A. Jones, MAJ, MC  
Ronald Sutherland, CPT, MC  
Deogracia Quinones, MAJ, MC  
Craig Donatucci, MAJ, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To provide an opportunity for urologists in training to develop expertise in the surgical techniques which are useful in the management of urinary tract trauma, to include renovascular surgery, renal autotransplantation, and use of various types of bowel segments for augmentation or substitution.

(16) Technical Approach: Animals are subjected, under anesthesia, to simulated urinary tract trauma. Various surgical procedures are performed to allow resident training in management of these situations.

(17) Progress: This is an important teaching protocol for urology.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/201 (3) Status: Terminated

(4) Title: Vasovasostomy in the Porcine Animal Model

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:  
Michael J. Raife, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Urology Svc

(10) Associate Investigators

(11) Key Words:  
vasectomy  
vasovasostomy  
microsurgery

Craig Donatucci, MAJ, MC  
Daniel W. Horne, LTC, MC  
Clyde R. Roy II, CPT, MC  
James B. Thrasher, CPT, MC  
Deogracia Quinones, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop and maintain microvascular surgical skills for vasovasostomy.

(16) Technical Approach: The vasa are isolated, severed, and reanastomosed using the operating microscope.

(17) Progress: Sufficient microsurgical experience is gained through protocol 84/20x-001. Request termination of this protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/209A (3) Status: Ongoing

(4) Title: Effects of Nonsteroidal Anti-inflammatory Agents on  
Tendon Healing

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Michael D. Getter, MAJ, MC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words:  
tendon healing  
non-steroidal anti-inflammatory  
agent

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if NSAID's effect heal rate of  
strength in rat tendon model.

(16) Technical Approach: Suture tendon laceration followed by haling  
with and without NSAID's.

(17) Progress: Re-evaluating method of administering medication,  
protocol not started.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/200 (3) Status: Completed

(4) Title: Military Boxing Related Injuries, Amended Protocol

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Robert W. Enzenauer, MAJ, MC

(9) Dept/Svc: SUR. Ophthalmology (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this investigation are the following: (a) to retrospectively determine the impact of significant boxing-related injuries on the US Army, (b) to determine the specific risk of ocular injuries sustained during an instructional boxing program, and (c) to evaluate the advisability of continued promotion of boxing in the military community.

(16) Technical Approach: See protocol.

(17) Progress: Protocol completed.

Publications:

Enzenauer RW, Montrey JS, Enzenauer RJ, and Mauldin M: Boxing-Related Injuries in the US Army, 1980 Through 1985. JAMA, 261:1463-1466, No. 10, March 1989.

Enzenauer RW, Mauldin M: A Retorspective Review of Ocular Injuries Associated with Military Boxing in the U.S. Army 1980-1985. So. Med. J., (Suppl.) 81(9):S47, 1988.

Presentations:

Enzenauer RW, Montrey JS, Enzenauer RJ, Mauldin WM: Boxing-Related Injuries in the US Army, 1980 Through 1985. Presented: Colorado Ophthalmological Society Annual Resident's Conference, 30 April 1988, Denver, CO.

Enzenauer RW, Mauldin WM: Boxing-Related Ocular Injuries in the US Army 1980-1985. Presented: 82nd Annual Scientific Assembly of the Southern Medical Association, Section on Ophthalmology, 7 Nov. 1988, New Orleans, LA.

Enzenauer RW, Montrey JS, Enzenauer RJ, Maulding WM: Boxing Injuries in the US Army, 1980-1985. Presented: Annual William Beaumont Trauma Symposium, 19 Nov 1988, El Paso, TX.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/202 (3) Status: Ongoing

(4) Title: Improving Cancer Management Through the Tumor Conference

(5) Start Date: (6) Est Compl Date: 1989-1990

(7) Principal Investigator: Jeffrey R. Clark, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Gen. Surg. Svc. (10) Associate Investigators  
Daniel T. Tell, MAJ, MC  
(11) Key Words: Harris W. Hollis, Jr., LTC, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IKC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 851  
d. Total Number of Subjects Enrolled to Date: 851  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: FAMC Tumor Board will be one of 22 in the state where in a randomized controlled fashion, multifaceted educational intervention (maintaining a randomly selected control group) will be introduced. The hypothesis is: Given emphasis on stimulating case presentations in a concert of patient management decision making, tumor boards can function as key elements in patient care and medical education.

(16) Technical Approach: The first 6 months will be baseline evaluation of tumor boards as they now exist. Then an interventional education package is randomly introduced to half the boards over one year and impact is seen. the other half receive no intervention. A crossover of intervention will occur after one year for one year's time. Then, six months of final analysis and recommendation made to NCI.

(17) Progress: Progress to date-FAMC is control and as such only attendance figures and case presentations are being forwarded to the project office to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/203 (3) Status: Ongoing

(4) Title: Comparison of Thermography and Standard Techniques for  
Detection, Diagnosis and Tracing of Disorders Marked by  
Altered Patterns of Peripheral Blood Flow

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics

(10) Associate Investigators

(11) Key Words:  
thermography  
pain

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 91

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area for patients with orthopedic related pain disorders.

(16) Technical Approach: We will make thermographic recordings of groups of ten subjects having one of the following conditions each time they come to Orthopedic Clinic from the initial diagnostic appointment through post-resolution follow-up: Frostbite, Charcot Joints, Carpel Tunnel Syndrome, Fibrositis, Sympathetic Dystrophy and Peripheral Neuropathy, Pre-amputation preparation, and Prediction of Bed Sore Formation. The clinical evaluations will not be related to the thermographic evaluations until the subject has completed participation in the study.

(17) Progress: This study is going smoothly but there are too few subjects in each group to determine the effectiveness of thermography for any of the groups begun to date.

Publications: None

Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/204 (3) Status: Ongoing

(4) Title: Mechanism Based Treatments of Phantom Limb Pain

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics

(10) Associate Investigators

(11) Key Words:  
phantom limb pain  
treatments

Timothy Young, MD, Augusta,  
VAMC  
Robert Rodinelli, MD,  
Denver, VAMC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 21  
d. Total Number of Subjects Enrolled to Date: 39  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate the effectiveness of treatments for burning phantom limb pain.

(16) Technical Approach: We will treat four groups of ten amputees each with the same six interventions. The amputees will be grouped by the description of their phantom pain. We will work with those describing their phantom pain as (1) only burning, (2) only cramping, (3) mixed cramping and burning, and (4) shooting / stabbing / shocking. Before treatment begins, there will be a three week baseline in which each amputee will be interviewed and stump muscle tension and heat outflow patterns will be recorded. Each amputee will receive each treatment for one month unless side effects force withdrawal. Treatment months will alternate with three week "washout" periods to permit phantom pain to return to baseline. The treatments will be: (1) topical application of nitroglycerine for mainly venous-side vasodilatative effects, (2) trental to reduce blood viscosity so more blood can reach tissues in the stump having compromised vascular beds, (3) Nifedipine as a Calcium channel blocker for its known peripheral vasodilatative effects, (4) Cyclobenzaprine for its ability to reduce spasms of local origin without interfering with muscle function, (5) muscle tension recognition and relaxation training for its proven ability to reduce microspasms and

tension related to intensification of phantom pain, and (6) body surface temperature recognition and control training for its ability to help people control vasodilation of peripheral vessels while under stress. Subjects will be recorded the same way they were during the baseline at each session to permit objective verification of physiological changes. They will come to the clinic every other week during treatments. At the end of the last treatment, there will be another three week baseline. Following the final baseline, the treatment which proved most effective, if any, will be continued for one year. Subjects will be recorded at monthly intervals. If no treatments are effective, subjects will still be followed for one year but will be recorded at six and twelve months.

(17) Progress: Treatment for burning and cramping pain are working well. Shocking/shooting pains do not respond for most subjects.

Publications:

Sherman R, Ernst J, Barja R, Bruno G: Phantom pain: A lesson in the necessity for carrying out careful clinical research in chronic pain problems. Rehabilitation Research and Development, 25(2): vii-x, 1988. (Editorial)

Sherman R, Barja R: Treatment of post-amputation and phantom limb pain. In (K. Foley and R. Payne, eds.) Current therapy of pain. B.C. Decker, Publisher, Ontario, 1988. (Chapter)

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 13(1):55, 1988. (Abstract)

Sherman R, Arena JG, Bruno GM, Smith JD: Precursor relationships between stress, physical activity, meteorological factors, and phantom limb pain: Results of six months of pain logs. Proceedings of the Joint meeting of the Canadian and American Pain Societies, Toronto Canada, November, 1988 (Abstract).

Sherman R: Phantom limb and stump pain. chapter in (R. Portenoy, ed) Neurologic Clinics of North America. W.B. Saunders Co., Publisher, 1989, (Chapter).

Sherman R, Sherman C, Grana A: Occurrence of acture muscle contractions in the residual limbs of amputees preceding acute episodes of phantom limb pain. Biofeedback and Self-Regulations, 1989 (Abstract).

Arena J, Sherman R, Bruno G: The relationship between humidity level, temperature, and phantom limb pain: Preliminary Analysis. Proceedings of the annual meeting of the Association for Applied Psychophysiology, 1989 (Abstract).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/205 (3) Status: Ongoing

(4) Title: Etiology of Low Back Pain Due to Muscle Tension

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators

(11) Key Words:  
low back pain  
environmental recording  
surface EMG

David Hahn, LTC, MC  
Timothy Young, MD, Augusta, VAMC  
Robert Rodinelli, Ph.D., Denver,  
VAMC  
Bertram Rothschild, Ph.D.,  
Denver, VAMC  
John Arena, Ph.D., Augusta, VAMC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 4  
d. Total Number of Subjects Enrolled to Date: 15  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the relationship between (a) the intensity and duration of work, (b) patterns of muscle tension, and (c) onset of low back pain. To determine whether patterns of muscle tension occurring during normal daily activities are different among people with (a) chronic low back pain, (b) intermittent pain, and (c) no pain. To determine relationships between patterns of muscle tension observed among relatively young active duty soldiers with intermittent low back pain and relatively older veterans with intermittent and chronic low back pain of muscle tension origin. To determine whether simple preventive measures can decrease intensity and frequency of episodes of pain by changing response patterns of low back muscle tension.

(16) Technical Approach: We will do two week long, continuous muscle tension, activity, and pain recordings of relatively young active duty soldiers with duties ranging from strenuous to sedentary who are either

pain free, report intermittent low back pain due to muscle tension, or report almost continuous low back pain due to muscle tension. We will do similar recordings of relatively older veterans having similar activity patterns and similar back pain problems. If we are able to identify abnormal patterns, we will provide people who clearly show these patterns with behaviorally oriented muscle control treatments or mild muscle relaxants in order to determine the effect of these interventions on muscle contractions patterns and pain.

(17) Progress: No problems have been encountered. When they are pain free, subjects who frequently report low back pain have low back muscle patterns similar to subjects who virtually never report low back pain. When experiencing low back pain, these subjects have very different patterns than pain free subjects. EMG increases prior to onset of low back pain.

#### Publications:

Sherman R, Sherman C: Relationships between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Biofeedback and Self-Regulation, 1989.

Sherman R, Sherman C: Relationship between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Biofeedback & Self-Regulation 14(2):168, 1989.

#### Presentations:

Sherman R, Arena JG, Searle J, Sherman CJ: Relationships between low back pain, stress, and continuous recordings of paraspinal surface EMG and movement in patients' normal environments. Presented: Joint meeting of the Canadian and American Pain Societies, Toronto, Canada, November, 1988.

Sherman R, Sherman C: Relationships between continuous environmental recordings of posterior trunk muscle tension and patterns of low back pain and tension headaches. Presented: Annual meeting of the Association for Applied Psychophysiology, San Diego, 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/206 (3) Status: Ongoing

(4) Title: Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain

(5) Start Date: 1987

(6) Est Compl Date: 1989

(7) Principal Investigator:  
Richard A. Sherman, MAJ, MS  
John G. Arena, Ph.D.

(8) Facility: FAMC  
Augusta, VAMC

(9) Dept/Svc: Clin. Invstgn.

(10) Associate Investigators  
David Hahn, LTC, MC

(11) Key Words:  
low back pain  
thermography  
surface EMG  
MMPI

Timothy Young, MD, Augusta, VAMC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 41  
d. Total Number of Subjects Enrolled to Date: 92  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To test the effectiveness of paraspinal surface EMG, the MMPI, videothermography, physical examination, and standard diagnostic procedures for ascertaining objective data concerning the patient's actual low back pain intensity and underlying physical problems.

(16) Technical Approach: We are in the process of performing paraspinal surface EMG and videothermographic recordings of at least 360 subjects with low back pain of six diagnostic categories and who hurt most while in one of six different positions (6 x 6 cell design with ten subjects in a group). Each subject is being recorded four times: Twice while their pain intensity is the same and twice while it varies up or down from the two similar recordings. Thus, each subject is recorded at between two and three pain intensities. This provides data on change with time while pain is constant. All of these subjects are given a modified version of the MMPI designed to differentiate between psychological factors and changes in responses due to presence or absence of low back pain. Each subject is also given a complete orthopedic physical examination and any standard diagnostic procedures not already well documented is done.

(17) Progress: Thermography is usually able to pick up low back disorders independently diagnosed as being related to nerve problems but is not sensitive to pain due to muscle tension in the low back. Surface EMG is sensitive in the opposite way. When the two tests are used together, they are very efficient at quickly and noninvasively determining the physiological cause of the back pain.

Publications:

Arena J, Sherman R, Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in different positions. Pain, 37:57-65, 1989.

Arena J, Sherman R, Bruno G: Professionals and low back pain patients expectations of differences in response patterns on the MMPI as a function of presence or absence of chronic pain. Biofeedback and Self-Regulation, 1989.

Arena J, Sherman R, Bruno G: Reliability of multiple surface electromyographic recordings of the paraspinal muscles among subjects with and without low back pain. Int. J. Psychophysiology, 1989.

Sherman R, Arena J, Bruno: Electromyographic recordings of low back pain subjects in different positions during low and high pain levels. Biofeedback and Self-Regulation, 1989.

Presentations:

Arena J, Sherman R, Bruno G, Young T: Reliability of paraspinal electromyographic recordings in low back pain and non-pain subjects. Presented: Am. Psychological Assoc., 1988.

Sherman R, Arena J, Bruno G, Young T: Electromyographic recordings of low back pain subjects in different positions vs. results of standard diagnosis. Presented: Am. Psychological Assoc, 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/207 (3) Status: Ongoing

(4) Title: Determination of Mechanisms of Phantom Limb Pain:  
Phase 2

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators

Michael D. Getter, MAJ, MC

(11) Key Words:  
phantom limb pain  
mechanisms

Timothy Young, MD, Augusta, VAMC  
Robert Rodinelli, MD, Ph.D.,  
Denver, VAMC  
Jeffrey Ginther, MAJ, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 24  
d. Total Number of Subjects Enrolled to Date: 24  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To use MRI, nerve recording, and other techniques to monitor veteran and active duty amputees who report shocking, shooting, and stabbing descriptors of phantom limb pain while they are experiencing various intensities of pain in order to ascertain the physiological changes which are related to changes in pain intensity.

(16) Technical Approach: We will carry out the pilot for a full proposal in which we would record groups of twenty active duty or veteran amputees four times. In the pilot, only two amputees from each group will participate. Two of the recordings will be at one particular pain intensity while the other two will be at two different intensities. This will permit factoring changes due to time from those due to changes in pain intensity. Each subject will be recorded at about weekly intervals but the exact timing will have to depend on when their pain intensity changes. The groups will consist of two amputees with (1) only stabbing phantom pain, (2) only shooting phantom pain, (3) only shocking phantom pain, (4) a combination of all three (which is common), and (5) no phantom pain. The fifth group of amputees without phantom pain is necessary

to further evaluate changes which occur in the normal stump over time so we can differentiate them from abnormal changes. We know from our experience in Phase I of this study that twenty is the minimum number of amputees we can have in a group due to normal physiological variability and in variability in reporting pain intensity. However, two per group will give us an idea of whether the following techniques are likely to show any differences at all. We propose to use MRI to record overall stump anatomy, plethysmography to record swelling and internal stump pressure, and signals from the neuroma to record responses to mechanical and other stimuli. Because of its invasive nature, we will carry out only one nerve signal study from the stump. For subjects who report phantom pain, we will perform the test on a day when they report the maximum phantom pain they usually experience. We will compare the results of this recording with those from pain free amputees. Due to its cost, we will do MRI recordings of only one subject per pilot group. Two MRI's will be done for each pilot subject. One will be while the subject is as pain free as they get and the other will be while they are experiencing the most pain they generally expect.

(17) Progress: Four amputees experiencing numerous acute episodes of cramping phantom pain had the surface muscle tension in their residual limbs recorded. They pressed a button during episodes of phantom pain. Temporal relationships between initiation of episodes and spasms in the limb were established. Spasms precede start of pain by more than reaction time so causes the phantom pain.

#### Publications:

Sherman R, Sherman C, Grana A: Occurrence of acute muscle contractions in the residual limbs of amputees preceeding acute episodes of phantom limb pain. Biofeedback & Self-Regulation 14(2):169, 1989.

Sherman R, Bruno G: Concurrent variation of burning phantom limb and stump pain with near surface blood flow in the stump. Orthopedics, 10:1395-1402, 1987.

Sherman R, Sherman C, Bruno G: Psychological factors influencing chronic phantom limb pain: An analysis of the literature. Pain, 28:285-295, 1987.

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 1988, (Abstract).

#### Presentations:

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Presented at the 19th Annual meeting of the Society for Applied Psychophysiology in Colorado Springs, CO, March 1988.



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/20x-003 (3) Status: Ongoing

(4) Title: Evaluation of the Goat as a Model for Bone Grafting  
Studies

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
David B. Hahn, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:  
Richard Sherman, MAJ, MS  
Ross M. Wilkins, MD  
Presbyterian Hospital

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: The overall objective is to determine the  
suitability of the goat as a model for studies on bone grafting.

(16) Technical Approach: See protocol

(17) Progress: We created 2cm defects in ulna in three goats. The  
goats were radiographed at three week intervals. Two out of three went  
on to heal their defects, thus bone grafts were not performed. We feel  
it is necessary to create a model that would consistently result in non-  
union. Plans are to do another preparatory study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/200 (3) Status: Ongoing

(4) Title: ALCON Surgical Intraocular Lens Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Floyd M. Cornell, LTC, MC

(9) Dept/Svc: SUR/Ophthalmology (10) Associate Investigators  
Jonathan Stock, MAJ, MC  
Ricardo J. Ramirez, MAJ, MC  
Eric A. Sieck, CPT, MC  
Thomas A. Gardner, CPT, MC  
John Pope, COL, MC  
Miles Whitaker, CPT, MC  
Robert W. Weller, CPT, MC  
William Walton, CPT, MC  
Roger K. George, CPT, MC

(11) Key Words:  
intraocular lens

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 11  
d. Total Number of Subjects Enrolled to Date: 25  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Adjunctive study with FDA for intraocular lenses used following cataract extraction.

(16) Technical Approach: Intraocular lenses are implanted into the anterior segment of the eye following cataract extraction either as a primary procedure or as a secondary procedure.

(17) Progress: All lenses in place are doing well. No adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/201A (3) Status: Ongoing

(4) Title: Use of Goats for Training in Advanced Trauma Life Support

(5) Start Date: 1988

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Stephen M. Fall, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Cardiothoracic

(10) Associate Investigators  
Dick R. Smith, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To conduct training courses in Advanced Trauma Life Support (ATLS).

(16) Technical Approach: See protocol

(17) Progress: 32 ATLS providers/instructors trained.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/202 (3) Status: Ongoing

(4) Title: A Comparison of Clinical Features of Ulnar Nerve  
Compression at the Elbow Before and After Medial  
Epicondylectomy

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: David Bizousky, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators  
James C. Johns, MAJ, MC  
Douglas Hemmler, CPT, MC

(11) Key Words:  
nerve compression  
conduction velocity

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 15  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: Assess results of medial epicondylectomy in the  
treatment of cubital tunnel syndrome.

(16) Technical Approach: Comparison of preoperative and postoperative  
and electrical parameters.

(17) Progress: Approximately 15 patients have undergone the procedure  
of medial epicondylectomy. Clinical impression is that operation is  
working well. No adverse reactions recorded.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/203 (3) Status: Ongoing

(4) Title: Evaluation of Current Nasal Surgical Techniques Used to Improve Nasal Obstruction (Subjective and Objective) Utilizing Anterior Rhinometric Techniques

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Michael L. Lepore, COL, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Otolyn/Hd&NkSur. (10) Associate Investigators

(11) Key Words:  
rhinomanometry  
nasal obstruction  
nasal surgery

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (a) to utilize anterior rhinometric principles in the pre-op assessment of patients prior to nasal surgery, (b) to utilize anterior rhinometric principles in the post-op evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery (opened or closed), and (c) to determine, utilizing anterior rhinomanometric techniques, if the unobstructive nasal cavity after nasal surgery (opened or closed) is significantly altered at the expense of correcting the pre-op obstructive side, and is this subjectively noted by the patient to the point of causing secondary obstructive symptoms, of any degree on the unobstructive side which will be objectively measured.

(16) Technical Approach: Measurements of nasal airflow utilizing anterior rhinomanometry will be performed before surgery and after surgery

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at definite periods. Correlation will be made between the various surgical procedures and the measured test results to note if any significant alterations on the unobstructed side have resulted from the surgical procedures.

(17) Progress: I have not initiated the project because of the following reasons: We are currently renovating our clinic and I was forced to move my equipment. It, unfortunately, cannot be set up until construction is completed. When the equipment arrived it was not functional and cable lines were damaged. This has been corrected.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) DATE: 30 Sep 89 (2) Protocol #: 88/205A (3) Status: Completed

(4) Title: The Use of Gore-Tex Soft Tissue Patches in Repair of Lid  
and Adnexal Defects in New Zealand White Rabbits

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Norman T. Byers, COL, MC

(9) Dept/Svc: SUR. Ophthalmology (10) Associate Investigators  
Eric A. Cohn, CPT, MC  
David R. Pernelli, CPT, MC

(11) Key Words:  
gor-tex  
lid repair

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 6 animals  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the animal species in question,  
the New Zealand White rabbit, will demonstrate specific orbital and  
anatomical considerations to enable further research in lid reconstruc-  
tion with Gore-Tex soft tissue patch (polytetrafluoroethylene-PTFE) for  
lid defects secondary to tumor or wartime injuries.

(16) Technical Approach:

(17) Progress: Completed

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/206A (3) Status: Ongoing

(4) Title: An Analysis of the Effect of Nonsteroidal Anti-Inflammatory Medications on Regeneration of Articular Cartilage in New Zealand White Rabbits Treated by Intermittent Active Motion and Continuous Passive Motion

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: Alexander Pruitt, MAJ, MC  
Anthony W. Colpini, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators  
Joe K. Ozaki, COL, MC  
Cris Myers, CPT, MC

(11) Key Words:  
articular cartilage regeneration  
continuous passive motion  
nonsteroidal anti-inflammatory

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The object of this protocol is to determine whether non-steroidal anti-inflammatory medications have an effect upon the regeneration of articular cartilage in rabbit knees. We are also attempting to delineate whether two separate nonsteroidal anti-inflammatories have different effects on regenerative of articular cartilage treated with continuous passive motion.

(16) Technical Approach: The rabbit knees will be arthrotomized and pieces of the articular cartilage will be moved and the knees will be closed, and then the rabbits will either be put on continuous passive motion on one leg and active intermittent motion on the other, after both arthrotomies. Then they will be reoperated at 4, 8 & 12 weeks, and one group will get no nonsteroidal, one group will get Piroxicam, one group will get Acetylsalicylic acid.

(17) Progress: Machine for "rabbit motion" is being modified by medical maintenance.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/207A (3) Status: Completed

(4) Title: Biomechanical and Histological Analysis of Achilles  
Tendon Healing After Open and Percutaneous Repair  
in a Rabbit Model

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Anthony W. Colpini, MAJ, MC

(9) Dept/Svc: SUR. Orthopedic (10) Associate Investigators  
Alexander Pruitt, MAJ, MC  
(11) Key Words: Joe K. Ozaki, COL, MC  
Cris Myers, CPT, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to compare the  
biomechanical strengths and histologic characteristics of healing  
Achilles tendon in rabbits that have been repaired using either an open  
or percutaneous technique.

(16) Technical Approach:

(17) Progress: Completed

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 88/208 (3) Status: Ongoing

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(4) Title: A Retrospective Analysis of the Incidence of  
Pseudarthrosis in Posterior Spine Fusion Done  
Between 1971 and 1986, at St. Anthony's Hospital  
and Denver Children's Hospital

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(5) Start Date: (6) Est Compl Date:

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(7) Principal Investigator: Alexander Pruitt, MAJ, MC  
John A. Odom, MD (8) Facility: FAMC  
Lakewood Clinic, Denver, CO

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(9) Dept/Svc: SUR. Orthopedic (10) Associate Investigators  
John L. Brugman, LTC, MC

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(11) Key Words:

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

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(15) Study Objective: The purpose of this study is to evaluate those  
patients with pseudarthrosis and compare them with an age, sex, and  
diagnosed matched group of controls who also underwent posterior spine  
fusion but did not develop pseudarthrosis. We propose to evaluate the  
contributions of several factors which may effect the incidence of  
pseudarthrosis in these patients.

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(16) Technical Approach:

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(17) Progress: Data is currently being put into the computer. Charts  
are still being reviewed.

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Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/209 (3) Status: Ongoing

(4) Title: A Comparison of Percutaneous Repair Versus Open Repair  
of Achilles Tendon Ruptures

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC  
R. Todd Hockenbury, CPT, MC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators  
James C. Johns, MAJ, MC  
Rick Wilkerson, MAJ, MC

(11) Key Words:  
achilles tendon ruptures  
percutaneous repair of achilles  
tendon ruptures

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: (a) To compare the clinical results of per-  
cutaneous repair to open repair of achilles tendon rupture and to inves-  
tigate the complications and long-term outcome of these techniques. (b)  
To compare the initial repair strengths of these techniques.

(16) Technical Approach: Patients are now being randomized into 2  
separate groups and surgery is being performed. The cadaver study is  
completed.

(17) Progress: Only 4 additional patients enrolled.

**Publications:**

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" (Submitted for publication, Journal of Foot and Ankle Surgery).

**Presentations:**

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: The Western Orthopaedic Society National Meeting. Honolulu, Hawaii, October 1988. Winner of the Vernon P. Thompson Award.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Foot and Ankle Society Section of The National Academy of Orthopedics Meeting. Las Vegas, Nevada, February 1989.

"A Biomechanical Comparison of Percutaneous Versus Open Repair of Achilles Tendon Defects" Presented: Rocky Mountain Chapter Meeting of the Western Orthopedic Society Barnard Lecture Competition. February 1988, and was selected as one of the five finalist papers.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/210 (3) Status: Ongoing

(4) Title: Delayed Repair of Traumatic Intratemporal Facial  
Nerve Palsy in the Pig

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
David M. Barrs, COL, MC

(9) Dept/Svc: SUR/Otolaryngology (10) Associate Investigators:

(11) Key Words:  
traumatic facial palsy  
nerve graft

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: a. Determine optimal timing for facial nerve repair following temporal bone trauma; b. measure effect of stretch injury to facial nerve in cerebellopontine angle; c. refine direct facial nerve stimulation technique in the temporal bone; and d. develop an animal model for facial nerve study in the temporal bone.

(16) Technical Approach: The facial nerve is cut in the temporal bone and nerve grafted at intervals from immediately to three months after trauma. Histologic and electrophysiologic examinations will determine differences in return of function for different times of repair.

(17) Progress: All surgery, electrophysiologic testing, axon counts, and statistical analysis have been completed. Current progress is limited to writing papers from the results. Objective "b" was not accomplished and was dropped from the study.

Publications and Presentations: A thesis for the American Laryngological, Rhinological, and Otological Society has been completed and forwarded September 5, 1989. If accepted, the thesis will probably be broken into two separate publications due to its length. Several other publications may also be written concerning the electrophysiologic testing.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/211 (3) Status: Ongoing

(4) Title: Double Blind Crossover Study of Cyclobenzaprine Versus Placebo in Patients with Primary Fibrositis: Correlation of Symtomatic Verus Thermographic Criteria of Improvement

(5) Start Date: Jan '90 (6) Est Compl Date: June '90

(7) Principal Investigator: Robert A. Coe, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedic (10) Associate Investigators: Alexander Pruitt, MAJ, MC  
Richard A. Sherman, MAJ, MS  
Douglas Hemler, MAJ, MC  
Sterling West, COL, MC

(11) Key Words: fibrositis  
flexeril  
thermography

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objectives of this study are to compare Flexeril versus Placebo in the treatment of fibrositis, and to evaluate how subjective improvement of either drug or placebo corresponds to normalization of the thermogram.

(16) Technical Approach: Forty patients will be randomized to either the placebo or Flexeril (30mg qhs) group for a seven week period. Pain logs will be used by the subjects. PIs will assess subjects using subject interview, MMPI, pain log, physical exam and thermogram. After a one month washout period, the subjects will be crossed over.

(17) Progress: The study was approved pending revision of the consent form. No progress was made. The original PI PCS'd and a new PI was enlisted. The new PI and AI found, after basic research, that a third leg of the study using Baclofen is indicated for fibrositis to improve the design of the original study. An amendment and revised consent form will be submitted for IRC review for the November, 1988, meeting.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/212 (3) Status: Ongoing

(4) Title: Prevention of Nosocomial Pneumonia and Gastroduodenal  
Ulcer Prevention in Mechanically-Ventilated Patients

(5) Start Date: Oct 89 (6) Est Compl Date: Oct 92

(7) Principal Investigator: Phillip L. Mallory, II, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Intensive Care (10) Associate Investigators:

(11) Key Words: nosocomial pneumonia  
gastroduodenal ulcer

Kevin Dwyer, MD  
Brant Thrasher, MD  
William Marx, MAJ, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To decrease the incidence of pneumonia (nosocomial) in mechanically ventilated patients receiving antiulcer prophylaxis.

(16) Technical Approach: 4 groups of patients will be sequentially assigned to high, low, and moderate risk (based on APACHE) score) to receive either Cimetidine and antacids; Cimetidine, antacids, Tobramycin, Polymixin B, Amphotericin; Famotidine or Sulcralfate; GI bleeding will be noted; routine cultures will be performed.

(17) Progress: No progress as of this date. Medical Research and Development Command recently funded this project.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/213 (3) Status: Ongoing

(4) Title: Investigational Plan for the Clinical Study of Silicone Intraocular Lenses Sponsored by Allergan Medical Optics

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Floyd M. Cornell, LTC, MC

(9) Dept/Svc: SURG/Ophthalmology (10) Associate Investigators:  
Eric Sieck, CPT, MC  
(11) Key Words: Miles Witaker, CPT, MC  
silicone IOL Jonathan Stock, MAJ, MC  
William Walton, CPT, MC  
Ricardo J. Ramirez, MAJ, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to establish the safety and efficacy of the silicone intraocular lens according to FDA regulations.

(16) Technical Approach: The technical approach is the standard surgical method of cataract extraction and lens implantation to treat visually disabling cataracts.

(17) Progress: Although no patients have been enrolled to date, we anticipate beginning patient enrollment during the period November 1989 through October 1989.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/214 (3) Status: Ongoing

(4) Title: Clinical Investigation of Intraocular Lenses in Minors  
Sponsored by COBURN Optical IND, Inc/Storz Ophthalmics  
Inc.

(5) Start Date: 1988 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Floyd Cornell, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ophthalmology (10) Associate Investigators:

(11) Key Words:  
minors  
IOL  
cataract extraction

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 4  
d. Total Number of Subjects Enrolled to Date: 4  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to evaluate the  
safety and efficacy of intraocular lenses in children.

(16) Technical Approach: Patients are selected based on inability to  
utilize spectacles, contact lenses, or the use of epikeratoplasty. Only  
posterior chamber lenses are utilized. The lenses are placed in the  
capsular bag when available, into the ciliary sulcus when appropriate,  
or sutured into place when sulcus fixation is otherwise not achievable.

(17) Progress: There have been two patients enrolled because of  
traumatic cataracts, two patients enrolled because of irregular  
astigmatism and/or lack of iris support. All patients were enrolled  
because of cataract formation to one degree or another as a result of  
trauma. All patients are achieving their preoperative best corrected  
visual acuity and having no adverse reactions to the lens implant.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 88 (2) Protocol WU#: 88/215 (3) Status: Ongoing

(4) Title: Continuous Environmental Recording of Activity, Headache,  
and Muscle Contraction Level Among Subjects with Tension,  
Migraine or No Headache

(5) Start Date: 1988

(6) Est Compl Date: 1989

(7) Principal Investigator:  
Richard A. Sherman, MAJ, MS

(8) Facility: FAMC

(9) Dept/Svc: Or hopedics

(10) Associate Investigators

Richard Calkins, COL, MC

(11) Key Words:

David Hahn, LTC, MC

headache

Crystal Sherman,

muscle tension

environmental recording

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 2  
d. Total Number of Subjects Enrolled to Date: 5  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine relationships between motion, muscle  
tension in the frontal and trapezius muscles, and onset and intensity  
of headaches among subjects recorded in their normal environments.

(16) Technical Approach: Subjects wear a small EMG and motion recorder  
during all working hours for one week. They keep an hourly log of types  
and activity and pain intensity while wearing the recorder.

(17) Progress: The patterns of muscle tension and movement were  
virtually identical for all back pain subjects during pain free periods  
and for the pain free control. The subjects with back pain almost  
always showed increases in muscle tension preceding increases in pain  
and decreases preceding decreases in pain. All five headache subjects  
showed relationships in which both stress and upper back muscle tension  
increased prior to increases in headache intensity and decreased prior  
to decreases in pain. Trial results indicate that changes in muscle  
tenison precede changes in pain so are causative rather than reactive.

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Publications:    None

Presentations:    Presented at the Annual Meeting of the Association for  
Applied Psychophysiology in San Diego, 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/200 (3) Status: Completed

(4) Title: Internal Fixation of Osteochondral Fractures:  
A Biomechanical Study on Human Cadavers

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Jeffrey M. Hrutkay, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:  
James C. Johns, Jr., MAJ, MC

(11) Key Words:  
internal fixation

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To gather data through biomechanical testing which may help support a relatively newer method of fixation of osteochondral fractures.

(16) Technical Approach: Create osteochondral fractures in cadaver knees and hips. Compare strength of method of internal fixation.

(17) Progress: Completed

Publications and Presentations: Submitted to Clinical Orthopedics and Related Research. Presented: Barnard Seminar, March 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/201 (3) Status: Terminated

(4) Title: The Relationship of White Blood Counts with the  
Perception of the Blue Field Entoptic Phenomenon

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Eric Sieck, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ophthalmology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Terminated Study

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/202 (3) Status: Ongoing

(4) Title: The Effect of Harvesting the Central One-third of the Patellar Tendon and Reapproximating the Medial and Lateral Edges of Patellofemoral Joint Mechanics in Cadavers

(5) Start Date: 1989

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Richard A.Schaefer, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics

(10) Associate Investigators:  
Scott D. Gillogly, MAJ, MC  
Alexander Pruitt, MAJ, MC

(11) Key Words:  
arthroscopy  
anterior cruciate ligament

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine differences in patellofemoral joint contact area and pressure resulting from two standard treatments after harvesting the central third of the patellar tendon for ACL reconstruction (suturing versus not suturing the cut edges).

(16) Technical Approach: The radiographic and patellofemoral joint contact area and pressure changes in cadavers pre- and post harvesting the central one-third of the patellar tendon will be investigated.

(17) Progress: No progress.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/203 (3) Status: Ongoing

(4) Title: Rates of Occurrence of Simultaneous and Independent  
Low Back Pain and Headache Among Patients with and  
without Chronic Pain

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard A. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:  
John G. Arena, Ph.D.  
(11) Key Words: Jeffrey R. Ginther, MAJ, MC  
Melissa Damiano, M.S.

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 26  
d. Total Number of Subjects Enrolled to Date: 26  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the temporal relationships between  
the above pain problems among subjects with and without chronic pain.

(16) Technical Approach: Survey deers eligible people with and without  
pain while they are waiting for appointment at FAMC.

(17) Progress: Surveys being distributed.

Publications and Presentations: Noned

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/204 (3) Status: Ongoing

(4) Title: Incidence of Multiresistance in Serial  
Gram-Negative Isolates from ICU's

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: William H. Marx, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/SICU

(10) Associate Investigators:

Jeffrey R. Clark, COL, MC

(11) Key Words:

Harris W. Hollis, Jr., LTC, MC

Leo A. Andron, LTC, MS

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to develop an antibiotogram for the SICU.

(16) Technical Approach: A panel of 17 antibiotics commonly used in the SICU, involving 2-4 dilutions will show gram-negative organisms drug resistance.

(17) Progress: Over 95 isolates from the FAMC SICU were tested with the 17 drug panel. Results are being analyzed to produce an antibiotogram.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/205A (3) Status: Ongoing

(4) Title: Correlation of the Vocal Fold Vibratory Pattern to the  
Post Operative Surgical Wound in the Porcine Model

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Don B. Blakeslee, LTC, MC

(9) Dept/Svc: SURG/Otolaryngology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Awaiting funding on the study.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/206A (3) Status: Ongoing

(4) Title: The Effect of Liposuction on Myocutaneous Flaps in the  
Yucatan Micro Pig

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Terence R. Woods, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Otolaryngology (10) Associate Investigators:  
Michael L. Lepore, COL, MC

(11) Key Words:  
swine  
liposuction  
myocutaneous flaps

(12) P Cumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effect of the timing of  
liposuction on the viability of the cutaneous portion of trapezius  
myocutaneous axial flaps created on the Yucatan Micro Pig.

(16) Technical Approach: See protocol

(17) Progress: Start date - November 1989

Publications and Presentations: None

(1) Date: 30 Sep 89 (2) Protocol #: 89/207 (3) Status: Ongoing

(4) Title: Etiology and Progression of Acute Muscle Tension Related  
Low Back Pain Occurring During Sustained Activity  
Including Combat Training Exercises

(5) Start Date: Oct 1989 (6) Est Compl Date: Sep 1992

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC  
& Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:  
David Hahn, LTC, MC  
(11) Key Words: Jeffrey R. Ginther, MAJ, MC  
low back pain John G. Arena, Ph.D.  
EMG (VA, Augusta, GA)

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: Determine the etiology and progression of acute  
muscle tension related low back pain occurring during sustained activity  
including combat training exercises.

(16) Technical Approach: Use ambulatory recorders to make second by  
second records of bilateral surface paraspinal EMG and back movement as  
well as hourly back pain and fatigue rating entries for 20 hours per day  
while subjects function in their normal environment.

(17) Progress: Funding approved by Medical Research and Development  
Command. Study due to begin in October.

Publications and Presentations: Noned

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/208 (3) Status: Terminated

(4) Title: LCSG 884 Assessment of 30-day Operative Morbidity for  
Surgical Resections in Lung Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Stephen Fall, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Cardiothoracic (10) Associate Investigators:  
Dr. Tom Gaines  
(11) Key Words: Dr. Carmello Otero

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 25  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To accumulate data on surgical procedures  
involving primary lung cancer to a 30-day interval.

(16) Technical Approach:

(17) Progress: Terminated due to lack of funding.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/209 (3) Status: Ongoing

(4) Title: Clinical Investigation of the Synthes Spinal  
Internal Fixator

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: David B. Hahn, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:  
Michael Getter, MAJ, MC  
(11) Key Words: spinal fixator Anthony P. Dwyer, MD  
(UCHSC)

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To verify the improved results of the surgical  
management of spinal fractures, that has been reported in Europe, with  
the use of the Synthes spinal internal fixator.

(16) Technical Approach: Phase II clinical trial to meet FDA  
requirements for release of this investigational new medical device.

(17) Progress: None to date. Protocol in abeyance pending  
determination from FDA regarding issuance of an Investigational Device  
Exemption.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/211 (3) Status: Ongoing

(4) Title: Randomization Study of Transurethral Resection of  
the Prostate vs Balloon Dilatation of the Prostate  
for Symptomatic Benign Prostatic Hyperplasia in Men

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 90

(7) Principal Investigator: Craig Donatucci, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Urology Svc (10) Associate Investigators:  
Michael Raife, COL, MC

(11) Key Words:  
transurethral resection of prostate (TURP)  
balloon dilatation of prostate (BDP)

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effectiveness of balloon  
dilatation of the prostate (BDP) to TURP in moderately symptomatic men  
over 45 who suffer from benign prostatic hyperplasia (BPH).

(16) Technical Approach: This is a multi-center, two-arm, randomized  
study to examine the efficacy of BDP in improving symptoms of urinary  
outlet obstruction and urinary flow in men with symptomatic BPH, and  
compare and contrast the results with those of men undergoing TURP. Men  
with urinary outlet obstruction who need TURP and meet the protocol  
entrance criteria will be randomly assigned to TURP or BDP. After  
operation the patients will be followed for 1 year to determine  
improvement in symptoms, urinary flow parameters and post void residual  
urines. Groups will be compared to determine whether any beneficial  
effects from BDP have occurred.

(17) Progress: None. This protocol is awaiting funding in FY90.  
Publications and Presentations: one.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/210 (3) Status: Ongoing

(4) Title: Use of Body Surface Heat Patterns for Predicting and  
Evaluating Acute Lower Extremity Pain Among Soldiers

(5) Start Date: Oct 89 (6) Est Compl Date: Sep 92

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Orthopedic Svc (10) Associate Investigators:  
Allyn Woerman, LTC, PT  
Ft. Sill, OK  
Kent Karstetter, CPT, MC  
FAMC

(11) Key Words:  
thermography  
lower extremity pain  
surface temperature

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To provide immediate, on-site diagnosis of stress  
fractures in the lower extremities of active duty soldiers using a  
comparison of high technology videothermography and bone scan with filed  
viable contact thermography and surface temperature probes.

(16) Technical Approach: Phase I) Use videothermography and standard  
physical evaluations to establish baselines for trainees initially  
entering service at Ft. Sill, OK. Repeat thermograms will be performed  
on all trainees reporting to the troop medical clinic for treatment of  
pain in their knees, lower legs, and feet. Thermography will be  
performed on a matched group of trainees who come in to the clinic for  
other problems. This will permit differentiation of changes which  
occur among most trainees from pathological changes.  
Phase II) Compare videothermograms, contact thermograms, bone scan and  
other recordings of 100 trainees and 100 relatively senior soldiers  
suspected of having stress fractures with similar evaluations of matched  
controls to establish the efficacy of low technology contact  
thermography for evaluation of stress fractures.

(17) Progress: None. This protocol is pending funding from Medical  
Research and Development Command.

Publications and Presentations: None.

DEPARTMENT OF CLINICAL INVESTIGATION



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 72/302 (3) Status: Completed

(4) Title: Comparison of Metabolic and Functional Changes in Defects of Platelet Function

(5) Start Date: 1972

(6) Est Compl Date:

(7) Principal Investigator:  
T.P. O'Barr, DAC

(8) Facility: FAMC

(9) Dept. of Clin Investigation

(10) Associate Investigators

(11) Key Words:

platelet function tests

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To correlate biochemical and functional parameters to gain a better understanding of the pathophysiology of the disorders of platelet function.

(16) Technical Approach: Platelet Function Studies: When indicated clinically, platelet counts, bleeding times, platelet adhesion, and whole blood and PRP aggregation in response to ADP, collagen, epinephrine, or ristocetin will be performed in the Coagulation Section, Department of Pathology or the Biochemistry Service, Department of Clinical Investigation. Biochemical Studies: Assessment of the content and release of the content of the platelet's subcellular storage organelles (alpha and dense granules) and evaluation of the platelet membrane will include, but not be limited to the following: a) Electron microscopy and mepacrine staining of dense granules; b) Content of

platelet factor 4 and B-thromboglobulin activity in the alpha granules; c) Production of platelet-derived growth factor by 3H-thymidine incorporation in 3T3 mouse fibroblasts by platelet lysates; d) Measurement of secreted acid hydrolases (B-glucuronidase, B-galactosidase and membrane P-nitrophenyl phosphatase) activities; e) Membrane glycoprotein and phospholipid content; f) Release of arachidonate from membrane phospholipids by phospholipase C and diglyceride lipase; g) Mobilization of Ca<sup>++</sup>; h) Other studies as they become available.

(17) Progress: This study will be closed due to no principal investigator.

Presentations:

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDE): Reversal with Total Parenteral Alimentation (TPA). Presented: Western Society for Pediatric Research, Carmel, CA, February 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. Presented: III Congress International Society on Thrombosis and Hemostasis, Vienna, Austria, June 1973.

(3) Corby, D.G.: Mechanism of Platelet Dysfunction in Newborn Infant Presented: Society for Pediatric Research, APS-SPR, Washington, D.C., May 1974.

(4) Corby, D.G., Goad, W.C., Barber, J., and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. Presented: Vth International Congress on Thrombosis and Haemostasis, Philadelphia, Pennsylvania, June 1977.

(5) Corby, D.G., and O'Barr, T.P.: Decreased - Adrenergic Receptors Newborn Platelets: Cause of Abnormal Response to Epinephrine? Presented: VII Congress International Society of Thrombosis and Haemostasis, London, England, 1979.

Publications:

(1) Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimentation (TPA). (Abst.) Clin. Res. 21:304, 1973.

(2) Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P., and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. (Abst. p. 107), III Congress, Int. Soc. Thromb. Hemos. (Vienna, Austria), June 1973.

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- (3) Corby, D.G., (Intr. by Wm. E. Hathaway): Mechanism of Platelet Dysfunction in Newborn Infants. J. Ped. Res., Vol. 8, No. 4, April 1974.
- (4) Corby, D.G., Preston, K.A., O'Barr, T.P.: Adverse Effect of Gel Filtration of the Function of Human Platelets. Pro. Soc. Exp. Bio. & Med., 146:96-98, 1974.
- (5) Corby, D.G., Putnam, C.W., Greene, H.L.: Impaired Platelet Function in Glucose-6-Phosphatase Deficiency. The J. Ped., 85:71-76, July 1974.
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- (12) Corby, D.G., O'Barr, T.P.: Newborn Platelet Function. Chapter in Book, "Acquired Bleeding Disorder in Childhood". Masson Publ, p 31-37, 1981.
- (13) Corby, D.G., O'Barr, T.P., and Swanson, E.E.: Evidence for a Deficiency of Alpha-Granule Proteins in the Platelets of Newborn Infants. Soc. Ped. Res., May 1983.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 77/300 (3) Status: Ongoing

(4) Title: Immunologic Disorders in Children and Adults.  
I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies

(5) Start Date: 1977

(6) Est Compl Date: Open-Ended

(7) Principal Investigator:  
Robert S. Stewart, MAJ, MS

(8) Facility: FAMC

(9) Dept of Clin Investigation

(10) Associate Investigators  
John K. Podgore, COL, MC

(11) Key Words:  
immunologic diseases

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Oct 87 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: 199  
d. Total Number of Subjects Enrolled to Date: 1328  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Existing specialized immunochemical procedures will be consolidated into a registered protocol for use on a consultative basis by the FAMC hospital staff.

(16) Technical Approach: Serum gammopathies evaluated by SPEP, IEP, and rate nephelometry. Lymphocyte phenotyping, DNA analysis, and neutrophil activation potential by flow cytometry. Lymphocyte activation determined by quantitative mitogenesis.

(17) Progress: An additional 199 sample panels, representing 186 patients, were evaluated over this past year. These were distributed as follows: Leukemias: 20; Breast CA: 77; HIV: 43; Immunodeficiency Evaluations: 46; and Quality Assurance: 13. There was increasing interest in DNA evaluations of Breast CA as a possible indicator of success of therapy. New techniques are being evaluated to improve efficiency of lymphocyte transformation assay, integrating experimental radioimaging scanner in methodology.

**Presentations:**

(1) Brown, G.L., and Heggers, J.: Medical Mycology: Assessment of Bacteriologic and Serologic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(2) Dolan, W., Hill, S., Hasbargen, J., Rickman, W., and Weber, R.: Acquired Hypogammaglobulinemia with Absence of Leu-12 Antigen Following Bilateral Nephrectomy and Renal Transplantation for Goodpasture's Syndrome. Presented: 14th Annual Allergy--Immunology Symposium, Aurora, CO, 21-23 January 1986.

(3) Rickman, W.J., Lima, J.E., and Muehlbauer, S.L.: U.S. Army HTLV-III Testing Program Flow Cytometry Workshop. Presented: 11th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, San Antonio, TX, 18-20 March 1986.

(4) Rickman, W.J.: Epidemiology, Pathogenesis and Military Implications of HTLV-III Infection. Presented: Health Service Command Annual Pharmacy Conference. Aurora, CO, 5-9 May 1986.

(5) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Lymphocyte Subsets in Human Immunodeficiency Virus Infection: A Prospective Study. Presented: 2nd Annual Symposium of the Rocky Mountain Flow Cytometry Users Group, Albuquerque, New Mexico, 10-11 September 1986.

(6) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Human Immunodeficiency Virus (HIV) Natural History Study: Abnormal Proliferation of Leu-7 Positive Suppressor T Cells in Asymptomatic Seropositive Patients. Presented: United States Army AIDS Conference, Arlington, VA, 16-18 September 1986.

**Publications:**

Smolin, M.R., Hasbargen, J., and Rickman, W.J.: Profound Panhypogammaglobulinemia in a Renal Transplant Recipient. Ann. Int. Med. (in press) 1986.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 82/302 (3) Status: Ongoing

(4) Title: The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory

(5) Start Date: FY 84

(6) Est Compl Date: Ongoing

(7) Principal Investigator:  
Pari L. Morse

(8) Facility: FAMC

(9) Dept of Clin Investigation

(10) Associate Investigators

(11) Key Words:

microbiology

microbiological techniques

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_

d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within the laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: FY 89 - Two IFa test kits were evaluated for antibodies to CMV; FIAX CMV-G for IgG and FIAX CMV-M for IgM. We have found the FIAX CMV-G useful in the evaluation of AIDS patients. We have also evaluated an ELISA kit for Beta-2 Microglobulin in AIDS patients. We have not reached final conclusions on this kit as of yet.

Presentations:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented: a) Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; b) 5th Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985; ) 14th Aspen Conference on Pediatric Research, Aspen, CO, July 1985.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. J. Clin. Microbiol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/300 (3) Status: Ongoing

(4) Title: Early Identification of *Borrelia burgdorferi* Antibody  
in Human Sera

(5) Start Date: 1986

(6) Est Compl Date:

(7) Principal Investigator:  
Sandy L. Tessier, DAC

(8) Facility: FAMC

(9) Dept of Clin Investigation

(10) Associate Investigators  
Alan G. Barbour, MD, NIH  
Hamilton, MT  
Leo A. Andro, LTC, MS

(11) Key Words:  
borrelia  
lyme disease  
spirochete

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To develop a sensitive and specific screening  
assay to detect human IgM directed against *B. burgdorferi*. The  
procedure proposed here will determine if the avidinbiotin system can  
detect IgM antibody bound to *B. burgdorferi* on nitrocellulose paper  
(NCP).

(16) Technical Approach: Preliminary studies confirmed that the probes  
currently available against IgG are more sensitive and much more  
specific than the anti IgM probes. A new IFA kit using the FIAX  
fluorometer system that detects IgG/IgM antibodies to *B. burgdorferi* was  
found to have the best sensitivity and specificity of currently  
available commercial kits.

(17) Progress: We have received 582 serum samples (paired and unpaired)  
from soldiers at Ft. McCoy. 459 (including 12 controls) have been  
screened by ELISA and 250 of those have been FIAX-tested. One of the  
FIAX-tested sera, 94 are paired and in 23 of those soldiers spirochetes  
were recovered from the ticks. Eight samples of the 250 were FIAX  
positive, including 3 paired sera, indicating the soldiers were pre-  
exposed. The eight FIAX-positive samples were also ELISA positive and  
RPR negative. A manuscript is in preparation.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/30X (3) Status: Ongoing

(4) Title: Veterinarian and Veterinary Support Personnel Training in  
Emergency Care Procedures for Laboratory Animals

(5) Start Date: Jul 88 (6) Est Compl Date: Ongoing

(7) Principal Investigator: Creighton J. Trahan, MAJ, VC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:  
Terrie R. Clark

(11) Key Words:  
laboratory animals  
emergency procedures  
veterinary personnel training

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: N/A b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To provide veterinary resources personnel  
training in routine and emergency medical procedures in government owned  
animals.

(16) Technical Approach: See Protocol.

(17) Progress: No animals used under this protocol, to date.  
Fortunately, we have been able to conduct training on animals being  
terminated for other research protocols.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/300A (3) Status: Completed

(4) Title: Effect of Clonidine on Longitudinal Bone Growth in  
Juvenile Sprague-Dawley Rats

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
John K. Podgore, COL, MC

(9) Dept/Svc: Clin. Invstgn. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine if  
clonidine hydrochloride administration to juvenile rats, over a thirty  
day period, will increase longitudinal bone growth.

(16) Technical Approach:

(17) Progress: No difference noted among treatment and control groups.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/300A (3) Status: Ongoing

(4) Title: The Effect of the Topical Application of Minoxidil on Hair Growth in the "Nude" Mouse

(5) Start Date: 1989 (6) Est Compl Date: Dec. 1989

(7) Principal Investigator: Charles F. Ferris, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: T.P. O'Barr, Ph.D., DAC  
(11) Key Words: James E. Fitzpatrick, LTC, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 10  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To use athymic mice as a model to determine the possible method of action of minoxidil in the promotion of hair growth.

(16) Technical Approach: Minoxidil applied 2X daily on the 5 treatment mice, carrier on the 5 control animals. Biopsies taken baseline and at 3 week intervals for 12 weeks. Comparisons of hair growth will be made histologically.

(17) Progress: Histologic evaluations are pending.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/301 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: I Skin Lesion Examination

(5) Start Date: 1989 (6) Est Compl Date: 1991

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: Charles F. Ferris, MAJ, MS

(11) Key Words:  
lupus erythematosus  
immunofluorescence  
icam

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether systemic lupus erythematosus, discoid lupus erythematosus, and subacute lupus erythematosus can be differentiated by specific auto-antibody binding patterns in the skin using immunofluorescent staining techniques.

(16) Technical Approach: Direct immunofluorescence, immunoperoxidase staining, H&E histology.

(17) Progress: The project includes at present 20 patients we are still gathering data and patients.

Publications and Presentations: 2 papers in progress - 3 abstracts given.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/302 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: II Characterization of Autoantigens and Autoantibodies in Lupus

(5) Start Date: 1989 (6) Est Compl Date: 1992

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators: Charles F. Ferris, MAJ, MS  
Lela Lee, MD, UCHSC

(11) Key Words:  
neonatal lupus erythematosus  
autoantigens  
autoantibodies  
Ro

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The major objectives of this project are to characterize the autoantigens and autoantibodies involved in neonatal lupus erythematosus (NLE) and subacute cutaneous lupus erythematosus (SCLE) and to determine if certain characteristics of the autoantigens or autoantibodies can be related to the major clinical findings in these diseases.

(16) Technical Approach: Immunoblotting technique, cloning of Ro, rabbit immunization with Ro to attempt to produce animal model.

(17) Progress: Currently all phases are in progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/303 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: III The Study of the  
Effects of Ultraviolet Light on the Skin of Lupus  
Erythematosus Patients

(5) Start Date: 1989

(6) Est Compl Date: Unknown

(7) Principal Investigator:  
Scott Bennion, LTC, MC  
Lela Lee, MD

(8) Facility: FAMC  
UCHSC

(9) Dept/Svc: Dept Clin Invstgn

(10) Associate Investigators:  
Charles F. Ferris, MAJ, MS

(11) Key Words:  
ultraviolet light  
cutaneous lupus

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_

b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_

d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate and better correlate the cutaneous lupus subsets with their respective responses to ultraviolet light to be performed by phototesting patients with systemic lupus erythematosus (SLE), discoid lupus erythematosus (DLE) and subacute cutaneous lupus erythematosus (SCLE) then analyzing tissue and serologic specimens.

(16) Technical Approach: UV exposure followed by immunfluorescent.

(17) Progress: Study has not been started.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/304 (3) Status: Ongoing

(4) Title: Evaluation of the Protofluor-Z as a Screening Tool for  
Lead Intoxication in Children

(5) Start Date: 30 Aug 89 (6) Est Compl Date: 30 Aug 91

(7) Principal Investigator: Joseph C. White, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn (10) Associate Investigators:  
COL Askold Mosijczuk  
David B. Burgess, MD

(11) Key Words:  
blood lead  
heated graphite atomiztaion  
atomic absorption

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 400  
d. Total Number of Subjects Enrolled to Date: 400  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to reduce the cost of blood lead  
screening by placing hematofluorometers in a clinic setting. Only  
samples that fail the screening criteria need be analyzed further for  
anemia or lead intoxication.

(16) Technical Approach: Blood lead assayed by the gold standard  
method: atomic absorption, then reuslts compared with  
hematofluorometers measuring FPP.

(17) Progress: 400 samples assayed by aa; 300 samples assayed by  
hematofluorometer; methods developed for both instruments; certification  
of lab underway.

Publications and Presentations: None

DEPARTMENT OF CLINICAL INVESTIGATION

ANIMAL RESOURCES SERVICE

Training Support Summary

During the year, fourteen 91A, B, and C personnel from Emergency Medicine Service were trained in suturing techniques. Training consisted of an overview of operating room procedure, including aseptic technique, operating room rules of etiquette, instruction in the surgical scrub, proper gowning and gloving technique, and hands-on experience in dry and wet labs. Training was conducted on three days, using 14 rats. Forty-two hours of training were provided, requiring 18 hours of training support by Animal Resources Service personnel.

Thirty microsurgery training sessions were conducted, providing 97 hours of training to 69 staff surgeons and residents. Nine sessions were conducted for Orthopedic Service, 14 for Plastic Surgery Service, five for Otolaryngology Service, and two for Urology Service. Fifty-four hours of training support were required by Animal Resources Service personnel, and utilized 30 rats.

Two Advanced Trauma Life Support (ATLS) exercises were conducted during the year, using 8 goats in the training of 40 staff physicians in the emergency management of casualties. 160-plus hours of training were provided, requiring 100 hours of support by personnel of Animal Resources Service for planning, preparation, pre-op anesthesia induction, surgical preps, anesthesia monitoring, circulating and cleanup.

One renal trauma exercise was conducted by Urology Service, using one pig in the training of two staff physicians and three residents. Twenty-two hours of training were provided, requiring ten hours of support by Animal Resources Service personnel.

One kitten intubation exercise was conducted by Neonatology Service, using four kittens in the training of twelve physicians and nurses in methods of resuscitation and endotracheal intubation. Eighteen hours of training were provided, requiring eight hours of support by personnel of Animal Resources Service.

One kitten intubation exercise was conducted for The American College of Obstetricians and Gynecologists/Indian Health Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Ninety physicians and nurses received 135 hours of training in resuscitative methods and endotracheal intubation, using 13 kittens, and requiring 55 hours of support by personnel of Animal Resources Service.



### Cost of Training

|                         |              |              |                |
|-------------------------|--------------|--------------|----------------|
| Suture Labs (Rats)      | \$ 85/animal | x 14 animals | = \$1,190      |
| Microsurgery (Rats)     | 105/animal   | x 30 animals | = 3,150        |
| ATLS Exercises          | 225/animal   | x 8 animals  | = 1,800        |
| Renal Trauma Exercise   | 225/animal   | x 1 animal   | = 225          |
| Kitten Intubation, FAMC | 210/animal   | x 4 animals  | = 840          |
| Kitten Intubation, IHS  | 10/animal    | x 13 animals | = 130          |
|                         |              |              | <u>\$7,335</u> |

Under a Memorandum of Agreement, one high school senior from the Allied Health Occupations program, Aurora Public Schools T.H. Pickens Technical Center, received 180 hours of on-the-job vocational training as a veterinary aide, requiring 269 hours of instruction and supervision by Animal Resources Service personnel.

DEPARTMENT OF OB-GYN

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/351 (3) Status: Ongoing

(4) Title: Section A: Master Protocol for Phase II Drug Studies in the  
Treatment of Advanced Recurrent Pelvic Malignancies  
GOG 26

(5) Start Date: 4/14/86 (6) Est Compl Date: Unknown

(7) Principal Investigator: (8) Facility: FAMC  
Mark E. Potter, MAJ, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study  
of cancer.

(16) Technical Approach: See protocol

(17) Progress: Master protocol that is still ongoing for many phase II  
agents.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 80/352 (3) Status: Ongoing

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(4) Title: Section C: A Phase II Trial of CIS-Platinum  
GOG 26

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(5) Start Date: 4/27/77 (6) Est Compl Date: Unknown

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(7) Principal Investigator: (8) Facility: FAMC  
Mark E. Potter, MAJ, MC

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(9) Dept of OB-GYN (10) Associate Investigators

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(11) Key Words:  
pelvic neoplasms

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 3  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

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(15) Study Objective: To participate in the GOG protocol in the study  
of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients; one partial remission. No serious  
adverse reactions.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/359 (3) Status: Ongoing

(4) Title: Section S: A Phase II Trial of VM26  
GOG 26

(5) Start Date: 7/9/84 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 4  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Four patients, three progressive disease, 1 stable. No adverse reactions.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/362 (3) Status: Completed

(4) Title: A Clinical-Pathologic Study of Stages I and II Uterine  
Sarcomas  
GOG 40

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 3  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study  
of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients, surgical-pathological study only, no  
adverse effects.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/369 (3) Status: Completed

(4) Title: The Treatment of Women With Malignant Tumors of The  
Ovarian Stroma with Combination VCR, Dactinomycin and  
Cytosan (Phase III)

GOG 54

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
George Phillips, COL, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study  
of cancer.

(16) Technical Approach: See protocol

(17) Progress: One patient who is living and free of disease. No  
adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/376 (3) Status: Completed

(4) Title: Ultrastructural Staging and Therapeutic Consideration in  
Small Cell Carcinoma of the Cervix (Phase II)  
GOG 66

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
George Phillips, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study  
of cancer.

(16) Technical Approach: See protocol

(17) Progress: One patient; surgical-pathological study only, no  
treatment involved, no adverse effects.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 80/378 (3) Status: Ongoing

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(4) Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease

GOG 72

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(5) Start Date: 12/20/83 (6) Est Compl Date: Unknown

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(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

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(9) Dept of OB-GYN (10) Associate Investigators

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(11) Key Words:  
pelvic neoplasms

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

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(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: One patient, surgical pathological study only, no treatment involved and no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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(1) Date: 30 Sep 89 (2) Protocol #: 80/379 (3) Status: Ongoing

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(4) Title: Early Stage I Vulvar Cancer Treated with Ipsilateral  
Superficial Inguinal Lymphadenectomy and Modified  
Radical Hemivulvectomy (Phase III)

GOG 74

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(5) Start Date: 10/17/83 (6) Est Compl Date: Unknown

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(7) Principal Investigator: (8) Facility: FAMC  
Mark E. Potter, MAJ, MC

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(9) Dept of OB-GYN (10) Associate Investigators

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(11) Key Words:  
pelvic neoplasms

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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

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(14) a. Date, Latest IRC Review: 3/89 b. Review Results Approved  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

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(15) Study Objective: To participate in the GOG protocol in the study  
of cancer.

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(16) Technical Approach: See protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/380 (3) Status: Ongoing

(4) Title: A Clinical Pathologic Study of Primary Malignant Melanoma  
of the Vulva Treated by Modified Radical Hemivulvectomy  
GOG 73

(5) Start Date: 11/1/83 (6) Est Compl Date: 1990

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study  
of cancer.

(16) Technical Approach: See protocol

(17) Progress: No patients entered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 82/35X-001 Status: Ongoing

(4) Title: Repair of Femoral Artery and Fallopian Tube of Rabbit  
and Rat

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Edward G. Lundblad, COL, MC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Continued training for staff and residents is essential.  
Experience will make it possible to evaluate suture material and  
techniques for publication.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/351 (3) Status: Ongoing

(4) Title: Danazol in the Treatment of Premenstrual Syndrome

(5) Start Date: 1985

(6) Est Compl Date: 1989

(7) Principal Investigator:  
Diane C. Garrow, CPT, MS

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators  
Edward Lundblad, COL, MC

(11) Key Words:  
pms  
therapy

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 5  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if Danazol is effective in treating symptoms of pre-menstrual syndrome.

(16) Technical Approach: A double-blind, cross-over, placebo study in which patients who have documented PMS are treated for 2 months with Danazol and 2 months with placebo. While being treated, patients keep a diary of thier symptoms.

(17) Progress: There appears to be significant improvement in PMS symptoms while using Danazol as opposed to placebo.

Publications and Presentations: Obstetrics and Gynecology, July 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 84/352 (3) Status: Terminated

(4) Title: Characterization of Steroid Hormones Produced by Short-Term Incubation of Luteal Cells Obtained from Macaca fascicularis with Induced Luteal Phase Defects

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Charles F. Ferris, CPT, MS

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators  
Donald G. Corby, COL, MC  
Albert H. McCullen, MAJ, VC  
Edward Lundblad, LTC, MC

(11) Key Words:  
corpus luteum  
intern

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 12 monkeys  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to determine if differences exist between control and luteal phase defect induced cycles in the short-term production of steroids significant during the mid-luteal phase of the menstrual cycle of monkeys. If differences exists, possible new therapy for specific types of infertility may be recommended.

(16) Technical Approach: Luteal cells are obtained 5-8 days post-ovulation by luteectomy. The luteectomy obtained cells are processed, then cultured for 3 hours. The supernatant will be assayed for pregnenolone, progesterone, 17OH progesterone and testosterone using RIA procedures. The differences in assay levels of the steroid production from the control and treated cells will be statistically measured using multiple mean tests.

(17) Progress: Protocol is terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89    2) Protocol #: 87/351    (3) Status: Ongoing

(4) Title: A Randomized Comparison of Hydroxyurea Versus 5-FU  
Infusion and Bolus Cisplatin as an Adjunct to Radiation  
Therapy in Patients with Stages II-B, III and IV-A  
Carcinoma of the Cervix and Negative Para-Aortic Nodes

GOG 85

(5) Start Date: 8/4/86

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Mark E. Potter, MAJ, MC.

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89    b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, one patient

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/353 (3) Status: Ongoing

(4) Title: Evaluation of Cisplatin, Etoposide, and Bleomycin  
Induction Followed by Vincristine, Dactinomycin and  
Cyclophosphamide Consolidation in Advanced Ovarian  
Germ Cell Tumors

GOG 90

(5) Start Date: 9/18/86

(6) Est Compl Date: 1991

(7) Principal Investigator:  
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period:             
d. Total Number of Subjects Enrolled to Date:             
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/354 (3) Status: Ongoing

(4) Title: Randomized Clinical Trial for the Treatment of Women with  
Selected Stage IAi & IAii & IBii Ovarian Cancer (Phase III)  
GOG 95

(5) Start Date: 9/22/86 (6) Est Compl Date: 1994

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/356 (3) Status: Ongoing

(4) Title: A Phase III Randomized Study of Cyclophosphamide and  
Cisplatin in Patients with Suboptimal Stage III and  
State IV Epithelial Ovarian Carcinoma Comparing Intensive  
and Non-Intensive Schedules

GOG 97

(5) Start Date: 12/1/86 (6) Est Compl Date: 1990

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept./Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: 4  
d. Total Number of Subjects Enrolled to Date: 7  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Seven patients; one partial response, alive with no  
evidence of disease; two alive NEO; four dead of disease. No adverse  
reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/357 (3) Status: Completed

(4) Title: Echinoycin in Advanced Pelvic Malignancies

GOG 26W

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
George L. Phillips, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_ 0 \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 1 \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient, progressive disease, no adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/358 (3) Status: Ongoing

(4) Title: Evaluation of Intraperitoneal Chromic Phosphate After  
Negative Second-Look Laparotomy in Ovarian Carcinoma

GOG 93

(5) Start Date: 6/1/87 (6) Est Compl Date: 1992

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: 3/89 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/359 (3) Status: Ongoing

(4) Title: Adjunctive Radiation Therapy in Intermediate Risk  
Endometrial Carcinoma

GOG 99

(5) Start Date: 6/1/87 (6) Est Compl Date: 1991

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_ 0 \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 0 \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/350 (3) Status: Ongoing

(4) Title: Radiation Therapy vs No Further Therapy in Selected  
Patients with Stage IB Invasive Carcinoma of the  
Cervix

GOG 92

(5) Start Date: 3/9/88

(6) Est Compl Date: 1992

(7) Principal Investigator:  
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_ 0 \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 0 \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/351 (3) Status: Ongoing

4) Title: A Phase II Study of the Treatment of Stage III and IV  
Disease of Advanced Endometrial Carcinoma and All Stages  
of Papillary Serious Carcinoma and Clear Cell Carcinoma  
of the Endometrium with Total Abdominal Radiation Therapy  
GOG 94

(5) Start Date: 12/22/86 (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC  
Mark E. Potter, MAJ, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/352 (3) Status: Completed

(4) Title: A Phase II Trial of N-Methylformamide in Patients  
with Advanced Pelvic Malignancies  
GOG 26V

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed, no patients.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as (amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/353 (3) Status: Completed

(4) Title: A Phase II Trial of Vinblastine (NSC#049842) in Patients  
with Advanced Pelvic Malignancies  
GOG 26Y

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/355 (3) Status: Ongoing

(4) Title: Intraperitoneal (SWOG8501) Intraperitoneal Cis-Platinum  
and Cyclophosphamide IV vs Intravenous Cis-Platinum  
and Cyclophosphamide IV in Patients with Optimal  
Stage III Ovarian Cancer

GOG 104

(5) Start Date: 6/15/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/356 (3) Status: Completed

(4) Title: A Phase II Trial of Mitomycin-C (NSC #26980) in Patients  
with Advanced Squamous Cell Carcinoma of the Cervix  
GOG 76J

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
George L. Phillips, COL, MC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/357 (3) Status: Completed

(4) Title: Phase Two Study of the Intraperitoneal Administration  
of Cisplatin (NSC#119875) and 5-Fluorouracil  
(NSC#19893) in Residual Ovarian Carcinoma  
GOG 102B

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George L. Phillips, COL, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:  
pelvic neoplasms

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group  
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/359 (3) Status: Ongoing

(4) Title: GOG Protocol I02A - Master Protocol for Intraperitoneal Drug Studies in Residual Ovarian Malignancies after Second-Look Surgery

(5) Start Date: 1/4/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators  
Francis J. Major, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/360 (3) Status: Ongoing

(4) Title: A Phase II Trial of Hydroxurea, DTIC and VP-16  
in Patients with Advanced Uterine Sarcomas

87C

(5) Start Date: 3/7/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: This study was approved pending approval of a revised consent form, to date we have not received the new consent form.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/350 (3) Status: Ongoing

(4) Title: A Phase II Trial of Echinomycin (NSC#E526417) in Patients  
with Advanced Squamous Cell Carcinoma of the Cervix

GOG 76H

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:  
echinoycin

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: Evaluation of the efficacy and safety of  
echinomycin in the treatment of patients with advanced squamous cell  
carcinoma of the cervix.

(16) Technical Approach: This is a non-randomized study; all patients  
will be treated identically.

(17) Progress: No patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/351 (3) Status: Ongoing

(4) Title: A Phase II Trial of VP-16 in Patients with Advanced  
or Recurrent Uterine Sarcoma

GOG 87D

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

VP-16  
uterine sarcoma

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To identify active drugs against each of the two major types of sarcomas which have a high recurrence rate and against which combination chemotherapy has not been effective. VP-16 has been included because it has been shown to have elicited some response in a very small sample and the data suggest the need for study in previously untreated patients.

(16) Technical Approach: This is a non-randomized study which will involve treating an average sample size of 30 evaluable patients per drug. This method allows for rapid replacement of ineffective agents.

(17) Progress: No patients have been enrolled at FAMC to date.

Publications and Presentations: None.



(1) Date: 30 Sep 89 (2) Protocol #: 89/352 (3) Status: Ongoing

(4) Title: A Phase II Evaluation of Preoperative Chemoradiation  
for Patients with Advanced Vulvar Cancer  
GOG 101

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Mark E. Potter, MAJ, MC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:  
preoperative chemoradiation  
vulvar cancer

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if using preoperative chemoradiotherapy will obviate the need for pelvic exenteration in patients with advanced vulvar cancer; will its use allow less extensive surgical resection without compromising survival or cure.

(16) Technical Approach: All patients will be treated with split-course radiotherapy to the primary lesion as well as chemotherapy. Only patients with positive groin nodes will receive additional radiotherapy to the groin and pelvic nodes. Four to eight weeks after radiotherapy is completed, all patients will have surgical resection of the primary tumor plus bilateral groin node dissection.

(17) Progress: No FAMC patients enrolled to date on this recently approved protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/353 (3) Status: Ongoing

(4) Title: A Phase II Study of Intraperitoneal Administration of  
Cisplatin (NSC#119875) and Recombinant Alpha 2 Interferon  
in Residual Ovarian Carcinoma

GOG 102C

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Mark Potter, MAJ, MC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:  
cisplatin  
interferon  
ovarian carcinoma

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of these two drugs used  
in combination when there has been a partial response to Cisplatin as  
determined by second-look surgery.

(16) Technical Approach: All patients accepted for inclusion in this  
study will receive the above-named drugs. Any dosage modifications will  
be based on the type and degree of toxicity, if any, and is carefully  
defined in the body of the protocol.

(17) Progress: No FAMC patients enrolled in this recently approved  
protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/354 (3) Status: Ongoing

(4) Title: A Randomized Study of Doxorubicin vs Doxorubicin Plus  
Cisplatin in Recurrent Endometrial Adenocarcinoma  
Previously Diagnosed as Primary Stage III or IV  
(Phase III)

GOG 107

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

doxorubicin

cisplatin

endometrial adenocarcinoma

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether the addition of cisplatin to doxorubicin offers significant improvement in the frequency of objective response, in the duration of progression-free interval and the length of survival as compared with the administration of doxorubicin alone.

(16) Technical Approach: Patients will be randomized to one of the two regimens and will be treated until the maximum tolerated dose of doxorubicin is reached or until there is progression of disease.

(17) Progress: No FAMC patients enrolled in this recently approved protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/355 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Cisplatin (NSC#119875)  
and Etoposide (VP-16) (NSC #141540) in Patients with  
Residual Ovarian Carcinoma (Phase II)  
GOG 102E

(5) Start Date: 1989 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:  
cisplatin  
etoposide  
carcinoma

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of these two drugs used  
in combination when there has been a partial response to Cisplatin as  
determined by second-look surgery.

(16) Technical Approach: 200 mgm/M2 of Etoposide and 100 mgm/M2 of  
Cisplatin every 4 weeks for six doses.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/356 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Alpha Recombinant Interferon (aIFN) in Residual Ovarian Carcinoma (Phase II)

GOG 102F

(5) Start Date: 1989 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:  
Interferon  
carcinoma

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of this agent when it is administered directly into the area where the tumor is localized when there has been a partial response to Cisplatin.

(16) Technical Approach: 50x10<sup>6</sup> units of Interferon administered IP in 250ml NS after 1750 ml dialysate solution is given IP via the IP catheter. Therapy is given weekly for 12 weeks.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations:

DEPARTMENT OF PEDIATRICS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 78/40X-001 (3) Status: Ongoing

(4) Title: Use of Laboratory Animals (Cats) to Teach Medical Skills

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
C. Gilbert Frank, LTC, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators  
Beverly A. Anderson, MAJ, MC  
John P. Kinsella, MAJ, MC

(11) Key Words:

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Teaching protocol.

(16) Technical Approach: See protocol.

(17) Progress: Annual laboratory exercise continues to be successful in teaching intubation/chest tube placement skills to Pediatric House Officers. This remains an excellent model for teaching skills.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 82/403 (3) Status: Ongoing

(4) Title: Rare Tumor Protocol for Childhood Solid Tumor  
Malignancies, Ancillary  
POG 7799

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept of Pediatrics (10) Associate Investigators  
Thomas Carter, COL, MC  
(11) Key Words: POG protocol  
neoplasms Jeffrey Clark, COL, MC  
Randal Henderson, MAJ, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 2  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Two patients have been registered at FAMC, one pt. with  
superficial melanoma of the eye is continuing to do well, in complete  
remission. The other patient, a newborn with metastatic  
undifferentiated sarcoma of the face has died. The study remains open  
for new patient entry.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 82/414 (3) Status: Ongoing

(4) Title: NWTs Long Term Follow-Up Study: A Non-therapeutic Study  
POG 8158

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons, the study remains open to new patient registrations.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 82/420 (3) Status: Ongoing

(4) Title: Intergroup Rhabdomyosarcoma Study III

POG 8451

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators

(11) Key Words:  
drug therapy

Dr. Clark  
Dr. Reddy  
Dr. Henderson  
Dr. Bodlien

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 3  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Three patients have been entered at FAMC. The first patient has relapsed with metastatic disease after having completed the prescribed two years of chemotherapy and has died. Another patient, who entered in 1987 achieved complete remission status of his undifferentiated sarcoma of the pelvis region, but has subsequently died of overwhelming sepsis as a result of severe myelosuppression from chemotherapy. The other patient who was entered in 1988 with nasopharyngeal rhabdomyosarcoma is currently in complete remission status on chemotherapy. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/401 (3) Status: Ongoing

(4) Title: Prevalence of Endometriosis Externa in Adolescent Women Complaining of Severe Dysmenorrhea

(5) Start Date: 1983

(6) Est Compl Date:

(7) Principal Investigator:  
David W. Wells, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:  
endometriosis  
dysmenorrhea

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 622  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: An epidemiologic survey of young women will document the prevalence of symptomatic endometriosis externa in a middle class primary care population of adolescent women complaining of dysmenorrhea. This prevalent figure will tell the health care provider how alert he has to be to this condition.

(16) Technical Approach: This retrospective stage of epidemiologic survey is designed to isolate by questionnaire those young women who might have endometriosis and subject them to laparoscopy.

(17) Progress: No progress has been made on this protocol since the departure of the original principal investigator.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/402 (3) Status: Completed

(4) Title: B2 Microglobulin as a Measure of Renal Tubular Function  
in the Neonate

(5) Start Date: 1983

(6) Est Compl Date:

(7) Principal Investigator:  
Beverly Anderson, MAJ, MC

(8) Facility: FAMC  
St. Louis Children's Hospital  
Ronald Portman, MD, U. Texas at  
Houston  
Gerald B. Merenstein, MD, Univ.  
Colo. Health Sciences Center

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:  
kidney tubles  
natriuretic peptides

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 38

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of the study is to examine renal handling of low molecular weight proteins in the neonate at various gestational and postpartum ages who manifest evidence of normal or abnormal intrauterine environments as well as extrauterine insults. Recent data has shown that these insults can cause previously undiagnosed renal damage.

(16) Technical Approach: We will study the effects of these insults on the neonatal kidney from the standpoint of GFR as well as tubular function. These will both be evaluated in light of the rapid and profound changes in fluid and electrolytes in the first days of life. The protocol continues to be low risk as blood sampling is minimal. The protocol will clearly benefit the patient as renal damage from the aforementioned insults cannot be diagnosed in any other fashion with current technology.

(17) Progress: New developments in this field of research have made this study obsolete.

**Presentations:**

(1) Portman, R.J.: B2 Microglobulin as a Marker of Renal Tubular Injury in the Neonate. Presented: COMPRA, Aspen, CO 1984.

(2) Portman, R.J., Cole, J.: B2 Microglobulin as a Marker of Renal Tubular Injury in the Full Term Neonate with Meconium Stained Amniotic Fluid. Presented: National Student Forum for Research by Medical Students, New Orleans, LA, 1983. Winner of the best renal paper.

(3) Portman, R.J.: B2 Microglobulin as a Measure of Tubular Damage From Meconium Staining of the Amniotic Fluid. Presented: The USPS 1984 - Finalist for the Ogden Bruton Award.

(4) Portman, R.J.: B2 Microglobulin as a Marker of Renal Tubular Dysfunction. Presented: Society for Pediatric Research, San Francisco, CA, 1984.

(5) Portman, R.J., Anderson, B.: Atriopeptin as the Cause of the Diuresis in the Newborn in the First days of Life. Presented: COMPRA, Aspen, CO 1986.

**Publications:**

Cole, JW, Portman, RJ, Perlman, J, et al: Urinary B2 Microglobulin in Full Term Newborns: Evidence for Proximal Tubular Dysfunction in Infants with Meconium Stained Amniotic Fluid. Pediatrics, 76:958-964, 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/403 (3) Status: Ongoing

(4) Title: Prophylactic Intravenous Immunoglobulin for Infections  
in High Risk Neonates

(5) Start Date: March 86

(6) Est Compl Date: 1989

(7) Principal Investigator:  
C. Gilbert Frank, LTC, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators  
Beverly A. Anderson, MAJ, MC

(11) Key Words:  
high risk neonates  
prophylactic IVIG

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 21  
d. Total Number of Subjects Enrolled to  
Date: 4423 e. Note any adverse drug reactions  
reported to the FDA or sponsor for studying under an FDA-awarded IND.  
May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate in a double blind manner the effectiveness compared to an albumin placebo of IVIG preventing infectious disease and/or reducing morbidity and mortality in the high risk neonate.

(16) Technical Approach: < 2,000g, < 34 wks gestation are eligible for the study. Routine evaluations and therapy will be given as necessary to all infants. IgG antibody titers will be drawn pre and post infusion as well as at 1, 2, and 8 weeks. The incidence of infection as well as mortality and morbidity will be evaluated.

(17) Progress: This is a double-blind placebo controlled multicenter study administered out of Walter Reed and USHUS. Interim analysis will be performed by an FDA advisory panel on March 1989. Patient enrollment terminated April 1989 with completion of data collection in July 1989. Study presently in evaluation stage.

Publications and Presentations: Prophylactic Intravenous Immunoglobulin (IVIG) in High Risk Neonates. Presented. 16th Aspen Conference on Perinatal Research (ACPR) Aspen, CO July, 1987.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/406 (3) Status: Terminated

(4) Title: Infant Leukemia Protocol, A Group-Wide Pilot Study  
POG 8493

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One pt. was treated according to this protocol at FAMC after transferring from Brooke Army Medical Center. The child did well until approximately nine months after diagnosis when she developed progressive leukemia and subsequently died 10 months from diagnosis. Toxicity was mild to moderate myelosuppression with no other unusual toxicities. No new patients have been entered in the past year. The study is closed to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/408 (3) Status: Ongoing

(4) Title: Laboratory Classification in Acute Lymphoid Leukemia of  
Childhood (ALinC 14C) Phase III  
POG 8600

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept of Pediatrics

(10) Associate Investigators

(11) Key Words:  
drug therapy

Dr. Reddy  
Dr. Bodlien  
Dr. Henderson

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 7  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: During the past fiscal year, no new patients have been  
entered on study. Seven patients at FAMC are on this study, having been  
entered more than one year ago. One of those patients was entered at  
Walter Reed and transferred here. Since this is a laboratory  
classification study, there is no toxicity. The study is ongoing and is  
open to new pt. entry. One of the patients (MP) entered on study one  
year ago has a unique ALL phenotype. The patient has markers of T-cell  
ALL as well as being Philadelphia chromosome positive. This is a new  
finding in the protocol and in the Pediatric Oncology Group. The study  
is ongoing and is open to new patient entry.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/409 (3) Status: Completed

(4) Title: ALinC #14 Pharmacology: A Pediatric Oncology Group  
Non-Therapeutic Study  
POG 8601

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators

(11) Key Words:  
drug therapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 6  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: The study is ongoing but closed to new patient entry.  
Six patients at FAMC are currently on this study. This is a  
pharmacology study designed to measure Methotrexate and red cell folic  
acid metabolite levels. All six patients remain on study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/410 (3) Status: Ongoing

(4) Title: ALinC #14: Evaluation of Treatment Regimens in Acute  
Lymphoid Leukemia of Childhood (ALinC#14) - A Pediatric  
Oncology Group Phase III Study  
POG 8602

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators  
Dr. Reddy  
(11) Key Words: Dr. Bodlien  
drug therapy Dr. Henderson

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 5  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: There are currently five patients on this study. One of  
the five patients on study was entered at Walter Reed and transferred  
to FAMC. This patient has subsequently transferred to Roswell Park  
Memorial Institute in Buffalo, New York. A previous patient diagnosed  
at FAMC has subsequently been transferred to Travis Air Force Base and  
continues on protocol with information being related periodically to  
principal investigator at Fitzsimons. Significant toxicity in two of  
the five patients has included severe myelosuppression, septicemia in  
one patient, secondary to high-dose Methotrexate and high-dose Ara-C  
chemotherapy as per protocol. Otherwise, patients are tolerating  
therapy well and all remain in complete remission status, some having  
completed treatment. The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/401 (3) Status: Ongoing

(4) Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA Hodgkins Disease in Pediatric Patients, A Pediatric Oncology Group Phase III Study  
POG 8625/26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators  
Dr. Reddy  
(11) Key Words: drug therapy Dr. Bodlien  
Dr. Henderson

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient has been entered at FAMC. The patient achieved complete remission status and is currently doing well, having completed all therapy as per protocol. No unusual toxicities have been encountered. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/403 (3) Status: Ongoing

(4) Title: Randomized Phase II Study of Carboplatin (CBCDA) vs.  
CHIP in Treatment of Children with Progressive or  
Recurrent Brain Tumor  
POG 8638

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators  
Dr. Carter  
(11) Key Words: drug therapy Dr. REDdy  
Dr. Bodlien

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group  
in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient, a 14-year-old girl with recurrent pon- tine  
glioma was entered on this study in November of 1986. The patient is  
currently off chemotherapy, doing well with stable disease. Toxicity  
has been limited to moderate myelosuppression. The study is open to new  
patient entry, but limited to children with ependymoma or low grade  
astrocytoma.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/404 (3) Status: Ongoing

(4) Title: A Study of Childhood Soft Tissue Sarcomas (STS) Other  
than Rhabdomyosarcoma and Its Variants, A Pediatric  
Oncology Group Phase III Study  
POG 8653/54

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold D. Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators  
Dr. Clark  
(11) Key Words: Dr. Reddy  
drug therapy Dr. Bodlien

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group  
in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons. The study  
remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/405 (3) Status: Ongoing

(4) Title: Front Loading Chemotherapy in Children with Increased  
Risk Medulloblastoma  
POG 8695

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold D. Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators

(11) Key Words: drug therapy  
Dr. Carter  
Dr. Reddy  
Dr. Bodlien  
Dr. Henderson

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group  
in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient was entered at FAMC in April of 1987. The patient suffered severe grade IV myelosuppression secondary to the high-dose Cyclophosphamide as per protocol but recovered. However, during subsequent radiation therapy, the patient developed severe bone marrow hypoplasia lasting for two months but eventually recovered and refused further radiation therapy. He is currently off study, and is alive without tumor. Nationally, 34 patients have been entered on protocol. 22 patients are evaluable for response. Of these, the following post chemotherapy responses have been documented prior to radiation therapy: CR 6 patients, PR 3 patients, SD (stable disease) 5 patients, progressive disease 4 patients. Most important toxicity has been severe myelosuppression due to the high dose Cyclophosphamide which is expected. Although there have been 2-3 week delays in radiation therapy because of the myelosuppression, most patients have been able to complete chemotherapy and radiation as intended. The study remains open to new patient entry.

Publications and Presentations:

Dr. Mosijczuk presented an update on the status of the study at the Annual UCHSC Pediatric Hematology Seminar in Aspen, Colorado on March 31, 1989.

Dr. Mosijczuk presented an update on the status of the study at the Semi-annual Pediatric Oncology Group Meeting in Clearwater, Florida, April 1989.

Dr. Mosijczuk presented a poster abstract of the protocol results at the International Pediatric Neuro-Oncology meeting in Seattle, Washington on 2 June 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/406 (3) Status: Ongoing

(4) Title: Effects of Oral Contraceptive Agents on Coagulation  
Parameters in the Adolescent Patient

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Patrice T. Gaspard, MAJ, MC  
Vishnu Reddy, LTC, MC  
Judy Barber, DAC  
Patricia Rush, DAC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators

(11) Key Words:  
oral contraceptive agents  
thromboembolic disorders  
clotting factors

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 45  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To assess if the newer oral contraceptive agents  
used today have effects on the levels of clotting factors in adolescent  
patients (specifically Factor VIII, PT, PTT, fibrinogen, Antithromb III,  
and protein C).

(16) Technical Approach: Patients have the above studies measured at  
baseline, then 3 months, 6 months and one year after being on oral con-  
traceptives.

(17) Progress: Currently in process of analyzing data on computer  
patients to assess any trends. Following patients already enrolled but  
not entering any new patients until stats on current patients are  
analyzed.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/407 (3) Status: Completed

(4) Title: Headaches Among Adolescents

(5) Start Date:

(6) Est Compl Date: 1988

(7) Principal Investigator:  
Michael G. Schaffrinna, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: PED/Adolescent Med. (10) Associate Investigators  
Mark Blaedal, COL, MC

(11) Key Words:  
headaches  
adolescents

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 923  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine prevalence, type and sex distribution of headaches in adolescents.

(16) Technical Approach: Patients will be given the opportunity to fill out a headache questionnaire when they arrive at the adolescent medicine clinic. Questions were designed to evaluate any headache complaint according to type i.e., migrainous, muscle contraction (tension) or other. The data will then be evaluated to arrive at some demographic information.

(17) Progress: As recommended by the IRC a control trial of the questionnaire was started shortly after approval of the study. After 50 patients enrolled the questionnaire and results were analyzed and questions clarified where necessary or deleted. Current questionnaire began in July and results thus far are good. Of note is the presence of light headedness/dizziness in patients with tension headache. This has to my knowledge not been reported before. I am awaiting higher numbers before this finding will be as significant. FY 87 - finding a large number of patients are not aware that we can aid them with headaches. No adverse reactions. Questionnaire datais being analyzed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/408 (3) Status: Ongoing

(4) Title: Efficacy of Prophylactic Anti-Migraine Therapy in the Adolescent Therapy Patient - A Double Blinded Study

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Sharon Freeman, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: PED/Adolescent Med.

(10) Associate Investigators

MAJ Miller, MD

(11) Key Words:  
migraine headaches  
verapamil

LTC Dorsett, MD

Michael G. Schaffrinna, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_

b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_

d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine efficacy of prophylactic verapamil in a double blinded study in adolescent migraine sufferers. At the same time this study would establish a per kilogram dose for younger adolescents.

(16) Technical Approach: Patients will be evaluated at entry for the diagnosis of migraine headaches with a frequency per history of at least two events per month. Presence of organic disease will be evaluated via physical and laboratory evaluation. If no contraindications to verapamil exist then enrollment will occur. Over the next two months no medications will be given. The patient will see two different neurologists who will again evaluate them and fill out an interval history sheet. If both concur with the diagnosis, the patient will be randomly assigned by the pediatric pharmacy to receive either verapamil or placebo for two months. The patient will be seen every month for evaluation of therapy. At the end of two months, they will have a 7 day washout period. Then they will take the counterpart placebo or verapamil depending on which they were initially assigned. They will again take the drug for two months at which time the study will be completed.

(17) Progress: Due to time restraints and coordination problems we have not enrolled any patients up to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/400 (3) Status: Ongoing

(4) Title: T Cell#3 Protocol - A Pediatric Oncology Group Phase  
III Study

POG 8704

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators  
B. Vishnu Reddy, LTC, MC  
(11) Key Words: T cell ALL Randal Henderson, MAJ, MC  
John M. Bodlien, CPT, MS

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The one patient entered at FAMC (MP) is an eight-year-  
old girl who presented with an extremely high white count at diagnosis  
(852,000) and was found to have T-cell ALL. The patient responded well  
to initial leukopheresis and chemotherapy according to protocol. She  
relapsed 8 months from diagnosis and died. Toxicity has been the  
expected severe myelosuppression. The study remains open for new  
patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/401 (3) Status: Ongoing

(4) Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma  
in Children > 365 Days at Diagnosis

POG 8741/42

(5) Start Date: Dec 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators

B. Vishnu Reddy, LTC, MC  
Randal Henderson, MAJ, MC  
John M. Bodlien, CPT, MS  
Jeffrey R. Clark, COL, MC

(11) Key Words:  
treatment of stage D  
neuroblastoma

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC on this study.  
The study remains open for patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/402 (3) Status: Ongoing

(4) Title: The Effectiveness of Phase II Agents in Untreated  
Metastatic Osteosarcoma (MOS) or Unresectable Primary  
Osteosarcoma vs Previously Treated Recurrent Osteosarcoma  
POG 8759

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators  
B. Vishnu Reddy, LTC, MC  
David Hahn, LTC, MC  
(11) Key Words: phase II agents in untreated or recurrent osteosarcoma  
John M. Bodlien, CPT, MS  
Jeffrey R. Clark, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC on this study.  
The study remains open for patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/403 (3) Status: Ongoing

(4) Title: Evaluation of Response and Toxicity of Ifosfamide and  
VP-16-213 in Children with Resistant Malignant Tumors  
POG 8763

(5) Start Date: Dec 1987 (6) Est Compl Date: 1990

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators  
John M. Bodlien, CPT, MS

(11) Key Words:  
ifosfamide  
VP-16

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". ONE PATIENT WAS STARTED ON  
TREATMENT ACCORDING TO PROTOCOL ON A COMPASSIONATE BASIS FROM THE NCI.  
HE IS NOT OFFICIALLY ENTERED ON PROTOCOL.

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have officially been entered at FAMC on this  
study. One patient was treated according to protocol on a compas-  
sionate basis on a one time basis, and is doing well.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/404 (3) Status: Ongoing

(4) Title: Ceftriaxone vs Amoxicillin/Clavulanate for Initial  
Empirical Therapy of Occult Bacteremia in Children

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Frederic W. Bruhn, COL, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators  
John K. Podgore, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 187  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if one of the antibiotic regimens  
used for the empiric therapy of occult bacteremia will be more effective  
in preventing serious complications.

(16) Technical Approach: See protocol.

(17) Progress: Patient enrollment ongoing, preliminary data shows both  
therapies effective.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/405 (3) Status: Ongoing

(4) Title: Macromolecular Absorption in the Post-Asphyxiated  
Small Intestine of the Adult Rat

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Kevin J. Kelly, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators

(11) Key Words:  
macromolecular absorption  
asphyxial injury

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 48  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This protocol will attempt to demonstrate the mechanism of movement of whole protein macromolecules through small intestinal absorptive cells which have been subjected to an asphyxial injury, as compared to controls.

(16) Technical Approach: No new experimental techniques have been introduced. The animals are still anesthetized and subjected to laparotomy, as previously approved. The intestinal sacs constructed post-removal are now subjected to a new experimental variable. They are being incubated in the same nutrient media as previously described with the addition of a metabolic inhibitor 2,4 dinitrophenol. This will attempt to determine active vs. passive transport.



(17) Progress: To date, 48 animals have been used to expand the N values of both the control and experimental groups. To date, we have data on 16 gut sacs per group. It is very apparent that the experimental groups transport whole protein at a rate three times greater than the control groups. In addition, the metabolic inhibitor experiments preliminarily demonstrate total cessation of transport in both the experimental and control groups suggesting an active transport mechanism in both. These findings need to be confirmed in a larger sample of control and experimental animals as well as by light and electron microscopic evaluation. Once these experiments are completed, the gut sacs need to be then incubated from rats that have been pre-treated with therapeutic doses of theophylline. The sacs will then be exposed to the non-absorbable carbohydrate lactulose.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/406 (3) Status: Completed

(4) Title: Efficacy of Methylphenidate in Previously Undiagnosed  
Adolescents with Attention Deficit Disorders

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Joan R. Griffith MAJ, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators  
Bradford Miller, MAJ, MC  
Linda O. Ikle, Ph.D.

(11) Key Words:  
methylphenidate

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 22  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: The objectives of this study is to demonstrate the  
efficacy of methylphenidate in adolescents with learning problems in  
school accompanied by attention deficit disorders but previously un-  
dianosed or untreated in childhood.

(16) Technical Approach:

(17) Progress: Data gathering aspect of project has been completed and  
I am now in the process of analyzing the data for publication.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/407 (3) Status: Terminated

(4) Title: Comparison of Growth Response of Growth Hormone  
Deficient Children to Two Commercially Available  
Preparations of Growth Hormone

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Robert H. Slover, LTC, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e".

(15) Study Objective: In a randomized double-blind crossover study,  
growth response of growth hormone deficient children to two commercially  
available growth hormone preparations in equal doses will be compared  
to determine if there is any significant difference in growth response  
between the two. Growth hormone antibodies will be measured to  
determine if there is any significant difference in antigenicity.

(16) Technical Approach:

(17) Progress: Request termination because protocol was discontinued  
in Madigan. I do not have the number of patients at their facility.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/408 (3) Status: Ongoing

(4) Title: The Effect of Human/Animal Interaction on Stress  
Levels During Outpatient Pediatric Oncology Visits

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Mary Woolverton, MSW  
Terri R. Clark, CPT, VC

(9) Dept/Svc: Pediatrics (10) Associate Investigators  
Askold Mosijczuk, COL, MC

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 12  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's stress level as measured by blood pressure and fingertip temperature; b. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's anxiety level (as measured by behavioral questionnaires) or discomfort as measured by the visual analog pain scale).

(16) Technical Approach: Blood pressure, temperature and questionnaire will be used to evaluate stress levels in study subject.

(17) Progress: A total of 12 patients have been entered into the study. Due to investigators' time constraints we have not been able to gather data as projected.

Publications and Presentations: None

(1) Date: 30 Sep 89 (2) Protocol #: 88/409 (3) Status: Ongoing

(4) Title: The Correlation of Perinatal Events with Neonatal Morbidity: A Scoring System

(5) Start Date: Oct 88 (6) Est Compl Date: Oct 90

(7) Principal Investigator: Brian S. Carter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Neonatal (10) Associate Investigators: C. Gilbert Frank, LTC, MC

(11) Key Words:  
neonatal morbidity  
scoring system

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 500  
d. Total Number of Subjects Enrolled to Date: 1500  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To test the hypothesis that the combination of 3 commonly used means of fetal and neonatal assessment (fetal heart-rate tracings, umbilical arterial base deficit, and the 5 min. Apgar score) when combined in a scoring system can allow for the prediction of neonatal morbidity in the first 28 days of life.

(16) Technical Approach: A prospective, observational study. Enrollment is by chart review on all near-term (> 36 weeks gest.) newborns that had umbilical cord blood drawn in the delivery room, and were monitored in utero. Scores are assigned and the clinical courses observed for outcome.

(17) Progress: To date, progress has been slow but informative. At this point, the scoring system appears to be a valid means for making assessment of perinatal asphyxia, its severity and its consequences. Larger numbers are required for statistical power.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/410 (3) Status: Completed

(4) Title: Denver Developmental Screening Test

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: David Burgess, MD (8) Facility: FAMC

(9) Dept/Svc: PEDS/EFMP (10) Associate Investigators:

(11) Key Words:  
developmental screening

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 50  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Revision of the DDST to restandardize the test.

(16) Technical Approach:

(17) Progress: Completed study for subject enrollment, data is being analyzed at UCHSC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/400 (3) Status: Ongoing

(4) Title: Protocol for Second Induction and Maintenance in  
Childhood Acute Lymphoblastic Leukemia (SIMAL #5)

POG 8710

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold Mosijczuk, COL, MC

(9) Dept/Svc: PEDS/Hemo/Oncol (10) Associate Investigators:  
Dr. Reddy  
(11) Key Words: Dr. Bodlien

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/401 (3) Status: Ongoing

(4) Title: An Observational Study on the Response of Children to the Presence of a Stuffed Animal VS a Live Animal During a Neuromuscular Exam

(5) Start Date: 1988

(6) Est Compl Date: 1990

(7) Principal Investigator:  
Mary Woolverton, MSW  
Terri R. Clark, CPT, VC

(8) Facility: FAMC

(9) Dept/Svc: PEDS/EFMP

(10) Associate Investigators:  
David Hahn, LTC, MC

(11) Key Words:  
animal interaction  
stress reduction

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_

b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_

d. Total Number of Subjects Enrolled to Date: 26 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: By introducing an interaction with an animal we may be able to decrease anxiety and lessen the apprehension associated with potentially uncomfortable hospital visits.

(16) Technical Approach: See protocol

(17) Progress: Children seen in neuromuscular clinic are introduced first to a large white stuffed rabbit and later a dog/or cat to see how it effects their stress level during their physical exam in the clinic. This is documented on films and by independent observation. A total of 26 patients have been observed. This study is being actively pursued with more patients enrolled each month as they qualify by age and mental capacity.

Publications and Presentations: None



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/402 (3) Status: Ongoing

(4) Title: Newborn Informed Consent Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: C. Gilbert Frank, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Newborn Svc (10) Associate Investigators:  
Brian Carter, CPT, MC  
Patti Paige, MAJ, AN

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Evaluation of parental understanding of procedures and counseling performed following admission of their infant to the Newborn Intensive Care Unit.

(16) Technical Approach: Interview technique by single investigator with correlation of interview information with the medical record.

(17) Progress: Continued patient/parent enrollment and interviews.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/403 (3) Status: Ongoing

(4) Title: Effect of Inflammation in Chronic Pneumonia in Rats Due to Pseudomonas Aeruginosa----Medication by Bacterial Exoproducts

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: LeRoy M. Graham, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Pulmonary (10) Associate Investigators:

(11) Key Words:  
pneumonia  
pseudomonas aeruginosa  
rats

Michael L. Vasil, PhD  
Norbert F. Voelkel, MD  
Kurt R. Stenmark, MD

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Late. IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish an animal model for cystic fibrosis using rats.

(16) Technical Approach: See protocol

(17) Progress: Equipment being manufactured/purchased

Publications and Presentations: None

(1) Date: 30 Sep 89 (2) Protocol #: 89/404 (3) Status: Ongoing

(4) Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD)  
+ or - Low Dose Total Nodal Radiation Therapy in the  
Treatment of Stages IIB, IIIA-2, IIIB, IV Hodgkin's  
Disease in Pediatric Patients  
POG 8725

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold Mosijczuk, COL, MC

(9) Dept/Svc: PEDS/Hemo/Oncol (10) Associate Investigators:  
Dr. Reddy  
(11) Key Words: Dr. Clark  
Dr. Henderson  
Dr. Bodlien

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study  
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/405 (3) Status: Ongoing

(4) Title: Clonidine Treatment of Constitutional Delay of Growth and Puberty--A Prospective Double Blind Study

(5) Start Date: Sep 89 (6) Est Compl Date: Mar 91

(7) Principal Investigator: Robert Slover, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Adol Med (10) Associate Investigators: Linda Brantner, CPT, MC  
Linda Ikle, PhD

(11) Key Words:  
growth delay  
clonidine

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether chronic oral clonidine therapy is effective when compared to placebo in accelerating linear growth in constitutionally delayed pre-pubertal pediatric and adolescent patients.

(16) Technical Approach: Double-blind crossover study of 20 subjects.

(17) Progress: No progress. Original principal investigator PCS'd before starting the study. Dr. Slover will be the new PI.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/406 (3) Status: Ongoing

(4) Title: A Phase I Study of Hyperfractionation Radiation in Brain Stem Glioma in Children

POG 8495

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Askold Mosijczuk, COL, MC

(9) Dept/Svc: PEDS\Hema/Oncol (10) Associate Investigators:  
Dr. Carter  
(11) Key Words: Dr. Henderson

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 3  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: Three patients have been entered at FAMC. 2 patients with classic signs of high grade pontine glioma responded initially but subsequently relapsed. Another patient with symptoms consistent with low grade pontine glioma continues to do well two years after completing radiation treatment. Study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/407 (3) Status: Ongoing

(4) Title: Baby Development Follow-up Network Project

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Beverly A. Anderson, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Newborn

(10) Associate Investigators:  
Majorie Feinberg EFMP  
C. Gilbert Frank, MD

(11) Key Words:  
developmental evaluation  
high risk infants

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Developmental evaluation of all infants with birth weight of 1,000 to 1,500 grams who are Colorado residents.

(16) Technical Approach: The examinations will be done at 36-40 weeks post-conceptual age and eight months corrected age by physical or occupational therapists with at least one year experience in the Newborn Nursery who have been given special training sessions for this project.

(17) Progress: This is a new study, no subjects enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/408 (3) Status: Ongoing

(4) Title: Comparison of Cotinine Hair and Saliva Analysis in  
the Determination of Passive and Active Cigarette  
Smoking Exposure in Adolescents

(5) Start Date: Oct 89 (6) Est Compl Date: Oct 90

(7) Principal Investigator: Neil Goodman, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:  
Joseph White, MAJ, MS  
Ian Stewart, M.S.

(11) Key Words:  
cigarette smoke exposure  
passive smoking

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if commercially available EIA  
techniques for detecting cotinine correlate with historical survey to  
determine if the values accurately reflect the smoking history.

(16) Technical Approach: Small amounts of hair and saliva will  
obtained for EIA assay of cotinine from an adolescent population. A  
self-administered questionnaire detailing history of passive and active  
smoking over the preceeding 3 months will also be given.

(17) Progress: None. This study was recently approved by the IRC.

Publications and Presentations:

DEPARTMENT OF PATHOLOGY



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/450 (3) Status: Ongoing

(4) Title: Evaluation of the Available Plasma Separator Tubes  
for Storage of Patient Specimens

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Alan F. Weir, CPT, MS (8) Facility: FAMC

(9) Dept/Svc: Pathology (10) Associate Investigators:  
Margaret Zakroff, MT

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the difference between the current  
method and the newer serum separator tubes and the length of time serum  
can be stored using the new serum separator tubes.

(16) Technical Approach:

(17) Progress: This is a new approved study, principle investigator  
will report next FY.

Publications and Presentations:

DEPARTMENT OF RADIOLOGY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/602 (3) Status: Ongoing

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol  
(NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC  
Peter W. Blue, COL, MC

(9) Dept of Radiology/Nuc.Med. (10) Associate Investigators

(11) Key Words:  
adosterone  
adrenal glands

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep 87 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: None  
d. Total Number of Subjects Enrolled to Date: approx. 30  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent  
for the detection of adrenal cortical disorders and as a potential  
scanning agent for detecting structural abnormalities of the adrenal  
medulla.

(16) Technical Approach: Each patient will be studied while taking  
Lugol's or SSKI to protect thyroid. Some patients will have adrenal  
function suppressed with Dexamethasone. Following a 2 millicurie dose  
of NP-59, each patient will be scanned at day 3 and possibly day 5 and  
7.

(17) Progress: No studies were performed this period.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/600 (3) Status: Ongoing

(4) Title: a. The Usefulness of MRI and Transrectal Ultrasound in the Staging of Prostatic Cancer: Comparison to lmm Whole Gland Mounts. b. Artifacts and Variants of the Normal Prostate Seen by MRI and Transrectal Ultrasound: Comparison to lmm Whole Gland Mounts

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Kenneth D. Hopper, MAJ, MC  
Daniel Horne, LTC, MC  
David Thickman, MD  
Gary Miller, MD  
Gail Weingast, MD  
Michael Manco-Johnson, MD

(8) Facility: FAMC  
  
UCHSC  
UCHSC  
UCHSC  
UCHSC

(9) Dept of Radiology

(10) Associate Investigators  
Michael Raife, LTC, MC  
Edward Pienkos, LTC, MC  
Steve Parker, MAJ, MC  
Merlyn Gibson, MAJ, MC  
Jerry Sims, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 42  
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Within the past two years, the usefulness of transrectal ultrasound and MRI in the diagnosis and staging of prostatic cancer has been well demonstrated. There are numerous artifacts and variants within the prostate as seen with these two modalities, however, which are poorly understood. In addition, no study evaluating the efficacy of transrectal ultrasound and MRI in prostate cancer has compared the radiographic findings with histological mounts of the entire gland. We intend to correlate the results of the MRI and transrectal ultrasound to lmm whole gland mounts in order to better understand the aforementioned artifacts/variants as well as tumor extension.

(16) Technical Approach: See original protocol.

(17) Progress: The additional information provided by the ultrasound appeared to have a dramatic impact upon initial diagnosis. It paid much less role in staging. The MRI appears to have some significant benefits in staging.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/601 (3) Status: Ongoing

(4) Title: Body Fat Determination by Dual Photon Absorptiometry

(5) Start Date: 1988

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Peter W. Blue, COL, MC

(8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med.

(10) Associate Investigators  
Harry N. Tyler, Jr.

(11) Key Words:  
absorptiometry  
body fat

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ approx. \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studying under an FDA-awarded IND. May be continued on a separate  
sheet, and designated as "(14)e".

(15) Study Objective: To evaluate body fat composition by absorptiometry  
and other current modalities.

(16) Technical Approach: Each patient will be studied by four methods  
and the methods compared.

(17) Progress: No progress. To date funding is not available.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/602 (3) Status: Ongoing

(4) Title: The Comparative Renal Clearances of Disofenin and  
Mebrofenin

(5) Start Date: (6) Est Compl Date: July 1990

(7) Principal Investigator: Jay Cook MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators:  
Peter Blue, COL, MC

(11) Key Words:  
renal clearance  
disofenin  
mebrofenin

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The intent of the study is to objectively compare the renal serum clearance of each of the agents in the most optimally controlled environment possible, the individual patient. In this manner, the claims of the manufacturer can be established or refuted and the best agent determined.

(16) Technical Approach: The subjects will be categorized into normal (total serum bilirubin of less than 2.0), and four groups of abnormal (greater than 2.0, 5.0, 10.0 and 20.0). Each patient will then be given the minimal suggested dose (4 millicuries to 10 millicuries) and renal and hepatic clearances will be calculated. Hepatobiliary scans will also be performed on the patients with each agent. The abnormal group with bilirubins greater than 20 will receive the mebrofenin first followed by the disofenin to asses for competitive binding interference.

(17) Progress: Projects has not started yet, no patients have been tested.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/600 (3) Status: Completed

(4) Title: The Use of Ultrasound in Following Patients with  
Hydrocephalus

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Jay F. Cook, MAJ, MC (8) Facility: FAMC  
Childrens Hospital

(9) Dept/Svc: Radiology (10) Associate Investigators:  
Thomas Carter, COL, MC  
Steven Parker, MAJ, MC

(11) Key Words:  
hydrocephalus,  
ultrasound  
echoencephalography

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 23  
d. Total Number of Subjects Enrolled to Date: 23  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to demonstrate the usefulness  
of post operative ultrasonic evaluation of ventricular shunt  
function/malfunction.

(16) Technical Approach: Axial images obtained through the squamo-  
temporal bone.

(17) Progress: Completed.

Publications and Presentations: Submitted abstract to AIUM and will  
submit for publication in the Journal of Ultrasound.



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/601A (3) Status: Completed

(4) Title: Study #1. Analysis of Specimen Quality From the Four  
Currently Available Automatic Percutaneous Biopsy Needle  
Systems; Study #2. Comparison of Renal Damage Versus  
Specimen Quality Between the Vim Silverman Renal Biopsy  
Needle and the Bard Biopsy System

(5) Start Date: 1989 (6) Est Compl Date: 1989

(7) Principal Investigator: Kenneth D. Hopper, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: Study #1 will evaluate the quality of tissue  
obtained from the four currently available automatic biopsy systems.  
Study #2 will determine if the smaller less invasive Bard tru-cut needle  
system yields as good of a specimen with less renal damage than the  
standard Vim Silverman renal biopsy needle.

(16) Technical Approach: Pigs were used as the animal model.

(17) Progress: Data is being tabulated.

Publications and Presentations: Abstract presentation at the  
Radiological Society of North America 75th Annual Meeting, 26 Nov-1 Dec  
89, Chicago, IL.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/602 (3) Status: Ongoing

(4) Title: The Utility of the Bard "Biopty" Gun in the Breast:  
Correlation with Surgical Excisional Specimens

(5) Start Date: 1988 (6) Est Compl Date: 1990

(7) Principal Investigator: James Leuthke, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators:  
Steve H. Parker, MAJ, MC  
(11) Key Words: Bard "biopty" gun  
breast biopsy Jeffrey Lovin, CPT, MC  
Wayne Yakes, MAJ, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: 105  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To ascertain the accuracy of breast biopsies  
performed with the Bard "Biopty" biopsy gun utilizing stereotaxic  
mammagraphic and ultrasonographic guidance.

(16) Technical Approach: As outlined in objective.

(17) Progress: Results indicate that Bard "biopty" gun produces  
specimens as good as surgical biopsy.

Publications and Presentations: Abstract to be presented at the  
Radiological Society of North America 75th Annual Meeting,  
26 Nov-1 Dec 89, Chicago, IL, and to be published in Radiology.

(1) Date: 30 Sep 89 (2) Protocol #: 89/603A (3) Status: Completed

(4) Title: Study #3 - Comparison of Embolization of One Kidney with Absolute Ethanol Compared to the Other Kidney Embolized with Absolute Ethanol Mixed with Amipaque

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Wayne F. Yakes, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Radiology (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This study will determine the efficacy of alcohol embolotherapy. The degree of thrombosis and endothelial cell injury will be compared with the kidney that is embolized with absolute ethanol versus the opposite kidney embolized with absolute ethanol mixed with Amipaque.

(16) Technical Approach: See protocol.

(17) Progress: Study completed, tissue awaiting histological analysis.

Publications and Presentations: None

DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 80/650 (3) Status: Ongoing

(4) Title: A Study of Hemoglobin and of RED Cell Metabolism in the  
American Opossum (*Didelphis virginiana*)

(5) Start Date: 1980 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (3) Facility: FAMC  
Nicholas C. Bethlenfalvay, MD

(9) Dept/Svc: Primary Care (10) Associate Investigators:  
J.E. Lima

(11) Key Words:  
opossums  
red cells  
energy metabolism  
purine metabolism  
Elwyn Chadwick, SFC, USA

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: An inquiry into the energy metabolism of opossum  
red cells (glucose and purine nucleotide) involved in maintaining cell  
integrity and function.

(16) Technical Approach: Radiolabelled purine nucleosides, bases and  
glucose are provided to cells in-vitro and synthetic/catabolic pathways  
determined with the aid of HPLC/radiochromatography.

(17) Progress: Study results to date: Opossum red cells (but not  
mononuclear cells) are deficient in Adenosine Deaminase and their dATP  
content is half-millimolar. In contrast to human RBC, opossum red cells  
effectively utilize provided hypoxanthine for the production of ATP and  
GTP (J. Cell Physiol. submitted).

## Publications:

1. Petty C, Bethlenfalvay NC, and Bageant T: Spectrophotometric measurement of hemoglobin oxygen saturation in the opossum, Didelphis virginiana. Comp. biochem. Physiol. 50:273, 1975.
2. Bethlenfalvay NC, Block M, and Brown GB: Hemoglobins of the opossum (Didelphis virginiana Kerr) I. Developmental changes from yolk sac to definitive erythropoiesis. Lab. Animal Sci. 26:106-165, 1976.
3. Bethlenfalvay NC, Brown GL, and Waterman M: I. Hemoglobins of the opossum (Didelphis marsupialis) II. Electrophoretic and chromatographic observations. Lab Animal Sci. 26:908-912, 1976.
4. John ME, Bethlenfalvay NC, and Waterman MR: Oxidation - reduction properties of the hemoglobin of the opossum Didelphis Virginia. Comp. Biochem. Physiol. 73B:585-591, 1982.
5. Bethlenfalvay NC, Waterman MR, Lima JE, and Waldrup T: Cystolic and membrane bound methemoglobin reductases in erythrocytes of the opossum Didelphis virginiana. Comp. biochem. Physiol. 73B:594, 1982.
6. Bethlenfalvay NC, Waterman MR, Lima JE, and Waldrup T: Comparative aspects of methemoglobin formation and reduction in opossum Didelphis Virginia and human erythrocytes. Comp. Biochem. Physiol. 75A:635-639, 1983.
7. Bethlenfalvay NC, Lima JE, and Waldrup T: Studies on the energy metabolism of opossum (Didelphis Virginia) erythrocytes. I. Utilization of carbohydrates and purine nucleosides. J. Cellular Physiol. 120:69-74, 1984.
8. Bethlenfalvay NC, Lima J, Waldrup T, and Chadwick E: Studies of the energy metabolism of opossum Didelphis virginiana erythrocytes. II. Comparative aspects of 2-deoxy-D-glucose catabolism in opossum and human red cells in-vitro. Comp. biochem. Physiol. 89A:113, 1988.
9. Bethlenfalvay NC, Lima J, Stewart I, and Chadwick E: Studies on the energy metabolism of opossum Didelphis virginiana erythrocytes. III. Metabolic depletion with 2-deoxyglucose markedly accelerates methemoglobin reduction in opossum, but not in human erythrocytes. Comp. Biochem. Physiol. 89A:119, 1988.
10. Bethlenfalvay NC, Lima JE, Chadwick E: Studies on the energy metabolism of opossum Didelphis virginiana erythrocytes -IV. Half-millimolar levels of deoxy adenosine triphosphate in red cells are found associated with low adenosine deaminase activity. Life Sciences 44: 967-970, 1989.

Presentations: None

(1) Date: 30 Sep 89 (2) Protocol #: 87/650 (3) Status: Ongoing

(4) Title: Clonal Fidelity of Erythroid Lineage in  
Dyserythropoiesis: An Inquiry Into Ultrastructure

(5) Start Date: 1987 (6) Est Compl Date: Indefinite

(7) Principal Investigator: N.C. Bethlenfalvai, MD  
V.V. Reddy, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Primary Care (10) Associate Investigators:  
C.F. Ferris, MAJ, MS  
D.B. Mercill

(11) Key Words:  
dyserythropoiesis  
ultrastructure  
x-ray microanalysis

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate the aspects of ultrastructural components of erythroid precursors to include elemental composition of these components for determination of their role on erythroid maturation, morphology, the process of erythroid denucleation, and functional differentiation in various dyserythropoietic states.

(16) Technical Approach: Burst forming erythroid colonies will be grown in semi-solid tissue-culture media. Bursts will be isolated, fixed, embedded and evaluated by electron microscopy and concurrent x-ray microanalysis of metallic cellular inclusions.

(17) Progress: Initial culturing, staining, and consultation reveals that a new culturing system should be attempted.

Publications and Presentations: None

DEPARTMENT OF NURSING



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 86/700 (3) Status: Ongoing

(4) Title: Introduction of Suturing Techniques Using Outbred Adult Rats

(5) Start Date: (6) Est Compl Date: Indefinite

(7) Principal Investigator: LTC Lawrence A. Hammer, ANC (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators:

(11) Key Words:  
suture techniques training

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To instruct selected department of nursing personnel to properly suture traumatic lacerations, to establish and maintain a sterile field during the suturing procedure, to cleanse traumatic lacerations, to instruct the patient to manage the wound and facilitate healing, and to correctly remove suture when healing is complete.

(16) Technical Approach: Students are detailed to perform at least 1 successful suturing episode under direct supervision of an Emergency Medical Service staff physician to validate learning and clinical competence. Once certified, suturing activities become a part of the staff members' scopes of nursing practice. Skills are revalidated annually to ensure continued competence.

(17) Progress: Seventeen department of nursing personnel have completed the protocol during reporting period. All have been subsequently certified to perform basic suturing techniques in the FAMC Emergency Medical Service. No clinical practice deficiencies have been observed/reported which would indicate a problem with the revised protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/700 (3) Status: Ongoing

(4) Title: A Study of the Clinical Nurse Specialist in the AMEDD

5) Start Date: 1988

(6) Est Compl Date: 1989

(7) Principal Investigator:  
A.J. Frelin, COL, AN

(8) Facility: FAMC

(9) Dept/Svc: Nursing

(10) Associate Investigators

Nancy Staggers, MAJ, AN

(11) Key Words:  
role development

Ass. Prof., School of Nursing  
Univ. of California

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_

b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_

d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this descriptive study is to explore the role of the clinical nurse specialist (CNS) as implemented by the ANC from the perspective of the CNSs now in practice as well as the Nurse Managers where the roles are or could be implemented. (a) to describe the role of the CNS in HSC from the perspective of the practicing CNSs; (b) to describe the role of the CNS in HSC as perceived by ANC officers who rate/senior rate them and by Chiefs of Nursing Departments; (c) to compare the perceptions of these groups regarding role implementation; (d) to describe a normative profile of the ANC officer practicing in the CNS role and (e) to assess potential for the future implementation of this specialty in the ANC.

(16) Technical Approach: Each group will be surveyed using a written mailed survey instrument constructed for this purpose. Data analysis will be directed to describing the role and the normative characteristics of those practicing in the role.

(17) Progress: Principal data collection and analysis has been completed with the findings noted.

Presentations: Presented: 6th Annual Research Conference sponsored by the VA Medical Center and University of Utah, 17 Feb 89.

Publications: Pending publication.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/700 (3) Status: Completed

(4) Title: Time Spent in Non-Nursing Functions

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
A.J. Frelene, COL, AN

(9) Dept/Svc: Nursing (10) Associate Investigators:

(11) Key Words:  
non-nurse functions  
workload

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the percentage of time spent by nursing personnel in performing non-nursing tasks. To examine the thesis that obtaining the resources at an appropriate GS level to carry out non-nursing tasks could significantly improve the Department of Nursing's ability to meet mission requirements. Using the data obtained make recommendations for system solutions which would be sound both fiscally and for resource utilization.

(16) Technical Approach: The basic methodology was self-reporting with work sampling for reliability testing. Data analysis was carried out using descriptive statistics.

(17) Progress: Conclusions: Nursing personnel are spending significant amount of time carrying out non-nursing tasks; Personnel significantly underreported the amount of time they spent in these tasks; Since all tasks studied are appropriately carried out by personnel at the GS 4-5 level it would appear that it is fiscally wise to substitute these personnel for the more expensive nursing personnel; More nursing care would be made available if staff members were freed from non-nursing tasks.

Publications and Presentations: Seven presentations with 2 pending.

MEDDAC

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 83/902 (3) Status: Ongoing

(4) Title: Training Study, Emergency Medical Procedures

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Mark A. Larsen, COL, MC (8) Facility: FAMC  
Ft. Carson Vet. Activity &  
Ft. Carson MEDDAC Emergency  
Medical Service  
A-691-7226/7111

(9) Dept of Emerg Med & Vet Svc (10) Associate Investigators:

(11) Key Words:  
emergency medical services

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 99  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: This project is a refresher/teaching course in emergency medicine operative procedures. It is conducted on a monthly basis for EMS physicians and PAs'.

(16) Technical Approach: Under general anesthesia animals are subjected to common emergency medicine operative procedures including venous cutdown, peritoneal lavage, chest tube insertion, and thorocotomy with aortic cross clamp with cardiac laceration repair. At the end of the exercise, the animals are disposed of by lethal injection.

(17) Progress: Training program, good utilization and training continues.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 87/900 (3) Status: Completed

(4) Title: Serological Assessment of Lyme Disease Among Soldiers  
Training at Fort McCoy, Sparta, Wisconsin

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Michael W. Hastriter, MAJ, MC (8) Facility: FAMC  
For Leonard Wood, MO  
Preventive Medicine  
A-581-9471

(9) Dept/Svc: US Army MEDDAC (10) Associate Investigators:  
Leo A. Andron, LTC, MS  
Sandy Tessier

(11) Key Words:  
lyme disease  
ixodes dammini

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the number of cases of Lyme Disease contracted at the Fort McCoy among a small population of soldiers at high risk which are those soldiers bitten by a tick.

(16) Technical Approach: See protocol.

(17) Progress: Protocol is completed per telephone conversation with associate investigators.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/900 (3) Status: Ongoing

(4) Title: IOLAB Investigational Plan for the Clinical Study of  
Intraocular Lenses

(5) Start Date: 8/87 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Luis E. Colon, MAJ, MC (8) Facility: FAMC  
Fort Leonard Wood, MO  
65473-5700

(9) Dept/Svc: Ophthalmology Svc (10) Associate Investigators

(11) Key Words:  
IOL (posterior chamber)

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 21  
d. Total Number of Subjects Enrolled to Date: 46  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To establish the safety and effectiveness of  
intraocular lens implantation of the cataract patient.

(16) Technical Approach: Extracapsular cataract extraction with PC IOL  
secondary intraocular lens (IOL) implants.

(17) Progress: No adverse effects noted to date.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/901 (3) Status: Ongoing

(4) Title: Coburn Intraocular Lens Study AT GLWACH

(5) Start Date: 3/87

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Luis E. Colon, MAJ, MC

(8) Facility: FAMC  
Fort Leonard Wood, MO  
65473-5700

(9) Dept/Svc: Ophthalmology Svc

(10) Associate Investigators

(11) Key Words:

IOL (anterior chamber)

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 5  
d. Total Number of Subjects Enrolled to Date: 16  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To establish the safety and effectiveness of intraocular lens implantation of the cataract patient.

(16) Technical Approach: Secondary intraocular lens implant.

(17) Progress: No adverse effects noted to date.

Publications and Presentations: None



(1) Date: 30 Sep 89 (2) Protocol #: 89/900 (3) Status: Ongoing

(4) Title: Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610)  
for Immunization Against Q Fever

(5) Start Date: 1989 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Gary Clark, CPT, MC (8) Facility: FAMC  
US Army Health Clinics  
Dugway Proving Grounds  
Dugway, Utah 84022

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:  
immunization  
vaccine

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 22  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/901 (3) Status: Ongoing

(4) Title: Continued Evaluation of the Safety and Effectiveness  
of Venezuelan Equine Encephalomyelitis Vaccine, TC-83  
Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel  
IND 142

(5) Start Date: 1989 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Gary Clark, CPT, MC (8) Facility: FAMC  
Director of Health Services  
US Army Health Clinic, DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:  
immunization  
vaccine

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 22  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk  
workers.

(16) Technical Approach: Administered by U.S. Army Research Institute  
for Infectious Disease.

(17) Progress: End point of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/902 (3) Status: Ongoing

(4) Title: Evaluation of New Lots of Tularemia Vaccine, Protocol B:  
Comparative Assessment of Francisella tularensis  
Vaccine, Live, NDBR 101, IND 157

(5) Start Date: 1989 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Gary Clark, CPT, MC (8) Facility: FAMC  
Dugway Proving Grounds  
US Army Health Clinic

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:  
immunization  
vaccined

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 22  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk  
workers.

(16) Technical Approach: Administered by U.S. Army Research Institute  
for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/903 (3) Status: Ongoing

(4) Title: Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel, IND 914

(5) Start Date: 1989 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Gary Clark, CPT, MC (8) Facility: FAMC  
Director of Health Services  
DPG

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:  
immunization  
vaccine

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 22  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/904 (3) Status: Ongoing

(4) Title: Use of the Sixteen Personality Factor Questionnaire  
to Predict Susceptibility to Occupational Stress  
Among US Army Recruiters

(5) Start Date: Aug 89 (6) Est Compl Date: Aug 90

(7) Principal Investigator: John Kaicher, CPT, MC (8) Facility: FAMC  
US Army Health Clinic  
Ft. Sheridan, IL

(9) Dept/Svc: (10) Associate Investigators:  
Peter Orris, MD, MPH and  
Robert Moretti, PhD,  
Northwestern University  
Medical School  
Walter Teachout, CPT, MS, FAMC

(11) Key Words:  
occupational stress  
Army recruiters  
personality factors

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine a mechanism to identify those  
soldiers who are predisposed to disabling occupational stress problems,  
considerable psychopathological morbidity and its attendant costs.

(16) Technical Approach: To determine the validity of the 16PF to  
predict Army Recruiters predisposed to occupational stress related  
psychological and behavioral problems.

(17) Progress: Subject enrollment was recently initiated. No data  
yet available.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/905 (3) Status: Ongoing

(4) Title: Comparative Evaluation of Jet Injected PPD Based on the Mantoux Response in Initial Entry Training Soldiers

(5) Start Date: Oct 89 (6) Est Compl Date: Jul 90

(7) Principal Investigator: Karen Luther, CPT, An (8) Facility: FAMC Ft. Leonard Wood, MO

(9) Dept/Svc: Immunization Clinic (10) Associate Investigators: Niranjan Balliram, MAJ, AN

(11) Key Words: TB testing Mark Vandewalker, MAJ, MC Paul Howell, CPL

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To directly compare the jet-injected intradermal PPD to the stanedard Mantoux method for detection of TB exposure among IET soldiers at Fort Leonard Wood, MO.

(16) Technical Approach: Phase I) Jet injected response is compared to the Mantoux response in a convenience sample of known positive Mono-Vaccs assessing for the sensitivity and specificity against the gold standard. Phase II) Jet injected PPD is administered simultaneously with the Mono-Vacc to soldiers of unknown Mono-Vacc response and is evaluated as the single process of determining TB exposure among the IET soldiers at FLW.

(17) Progress: Subjects are currently being enrolled in the phase I pilot study.

Publications and Presentations: None.

COMPASSIONATE, EMERGENCY USE PROTOCOLS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 88/214 (3) Status: Ongoing

(4) Title: Compassionate Implant (Storz Ophthalmic Inc. Co.)

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: COL Floyd M. Cornell (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Approved by the IRC August 1988 and assigned #88/214.

Publications and Presentations:



FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/113 (3) Status: Ongoing

(4) Title: LCSG NC3

(5) Start Date: 1989

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_ 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Natural history study for patients with stage II non-small cell lung cancer.

(16) Technical Approach: See protocol.

(17) Progress: One-time enrollment of a patient approved in March 1989. Full IRC approval of protocol as 89/113 was given in May 1989.

Publications and Presentations: NA

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: (3) Status: Ongoing

(4) Title: POG 8743

(5) Start Date: 1989

(6) Est Compl Date:

(7) Principal Investigator:  
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Ped Hem-Onc

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment study for stage IV neuroblastoma sponsored by NCI.

(16) Technical Approach: See protocol.

(17) Progress: One patient enrolled to date who continues to do well.

Publications and Presentations: NA

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: (3) Status: Completed

(4) Title: Clinical Study for Severely Hearing Impaired Adults

(5) Start Date: Nov 1988 (6) Est Compl Date: 1989

(7) Principal Investigator: David M. Barr, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Surgery/Otolaryngol (10) Associate Investigators:

(11) Key Words:  
cochlear implant

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To restore some degree of hearing in severely hearing impaired adults.

(16) Technical Approach: Surgical implant of cochlear device.

(17) Progress: One patient who met all the enrollment criteria was given a cochlear implanted. Improved hearing was reported; however, hearing was not restored to the degree anticipated by the patient.

Publications and Presentations: NA

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: (3) Status: Ongoing

(4) Title: POG 8633/34 Treatment of Children Less than Three Years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation.

(5) Start Date: 1989 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Ped Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Patient treatment with NCI approved protocol.

(16) Technical Approach: See protocol.

(17) Progress: One patient enrolled for treatment of ependymoma of posterior fossa. Patient continues to do well.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: (3) Status: Terminated

(4) Title: Experimental Drug "Ofloxacin"

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
COL Michael E. Perry

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Use of experimental drug to treat patient suffering from tuberculosis.

(16) Technical Approach:

(17) Progress: Patient cured by use of Ofloxacin.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: (3) Status: Completed

(4) Title: Compassionate Use of NCI Protocol I-88-14

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
MAJ David S. Brantley

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress:

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: (3) Status:

(4) Title: Compassionate Enrollment in POG 8696/97

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: COL Askold Mosijczuk (8) Facility: FAMC

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Report Pending

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: (3) Status: Completed

(4) Title: Compassionate IND #124001487 Carboplatin

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC  
Col George Phillips

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Cancer treatment with investigational new drug.

(16) Technical Approach:

(17) Progress: Completed

Publications and Presentations:



FAMC A.P.R. (RCS MED 300, Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 89 (2) Protocol #: 89/406 (3) Status: Ongoing

(4) Title: Compassionate Use of POG 8495 "A Phase I Study of  
Hyperfractionation in Brain Stem Glioma in Children"

(5) Start Date: 1988 (6) Est Compl Date:

(7) Principal Investigator: COL Askold Mosijczuk (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND. May be continued on a  
separate sheet, and designated as "(14)e"

(15) Study Objective: Treatment with NCI approved protocol.

(16) Technical Approach: See protocol.

(17) Progress: This protocol was approved in June 1989 by the IRC for  
multiple patient enrollment. Original patient doing well.

Publications and Presentations: None

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